VOLUME 9 NUMBER 10

Food·Drug·Cosmetic Law

Journal

OCTOBER • 1954

Restitution—Modern Application of an Ancient Remedy . . . . . .
WILLIAM W. GOODRICH

A Report from England . . . . . .
CHARLES A. ADAMS, C. B. E.

California's Part in Food and Drug Law
WAYNE D. HUDSON

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A COMMERCE CLEARING HOUSE PUBLICATION

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The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need.

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FOOD DRUG COSMETIC LAW JOURNAL

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About the Authors

William W. Goodrich is Assistant General Counsel, Food and Drug Division, Department of Health, Education, and Welfare. He discusses the doctrine of restitution in its application to food and drug cases in an article derived from an address delivered before the Division of Food, Drug and Cosmetic Law in the Section of Corporation, Banking and Business Law of the American Bar Association at Chicago on August 17, 1954.

Charles A. Adams, C. B. E., whose paper was read at the same meeting, was formerly director of the Food Standards and Labelling Division in the United Kingdom Ministry of Food. He has served on the council of the Society of Public Analysts, and is a past vice president of that society. Mr. Adams is on the Lawyers Advisory Committee of The Food Law Institute.

Once a food law fellow in the graduate program at New York University under the auspices of The Food Law Institute, **Wayne D. Hudson** went on to teach the first undergraduate course in food and drug law at the Stanford Law School. He is now Deputy Attorney General of California.

Roy C. Newton, vice president of Swift & Company, in charge of research, in 1940 organized—for the American Chemical Society—the National Chemical Exposition held in Chicago, together with the Industrial Chemical Conference at the time of the exposition. Dr. Newton is past chairman of the society's Division of Agricultural and Food Chemistry, and for ten years was a member of the board of directors of the Chicago section. During one term he was chairman of that board. He is also past chairman of the Committee on Commercial Analysis of Fats and Oils of the American Oil Chemists' Society, and of its Committee for Review of Scientific Literature on Fats and Oils.

His article in this October JOURNAL, together with the four following it, is from a panel discussion on regulation of new chemical additives in food, held at the August ABA meeting.

As chemical-research vice president of The Quaker Oats Company, **Fredus N. Peters** continues an association with that organization which began upon his leaving school almost 30 years ago. Holding B. A. and M. A. degrees from the University of Missouri and a Ph. D. from the University of Wisconsin, Dr. Peters on December 8, 1925, took his first job with Quaker—as a research chemist in Miner Laboratories on a fellowship supported by Quaker. He is a member of numerous societies in the field of chemistry, as well as of various scientific fraternities.

Paul Logue, of St. Louis, is manager of market development for the Inorganic Chemicals Division of Monsanto Chemical Company. He served in several research positions both before and after joining Monsanto until he transferred into sales development work for the company in 1938. He became technical sales director for its Phosphate Division in 1950, and was named to his present position in 1952.

Fred Bartenstein, Jr., a member of the JOURNAL'S editorial advisory board, is counsel for Merck & Company, Inc., of Rahway, New Jersey. He has been a contributor to these pages since 1948.

Counsel for the American Bakers Association, **Joseph M. Creed** is a member of the District of Columbia bar.

George L. Maison, M. D., is president of Riker Laboratories, Inc., located in Los Angeles. His article—as with Mr. Hudson's—originally was an address delivered at the Public Conference on the Food and Drug Law held in Los Angeles on May 15, 1954, under the joint sponsorship of the University of Southern California School of Law, The Food Law Institute and the Women's Division of the Los Angeles Chamber of Commerce.

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Restitution—Modern Application of an Ancient Remedy

By WILLIAM W. GOODRICH

Mr. Goodrich Addressed the Division of Food, Drug and Cosmetic Law, Section on Corporation, Banking and Business Law, American Bar Association, at Chicago August 17

LAST APRIL, A JUDGE of the Supreme Court of Texas gave some excellent advice to newly admitted members of the bar, advice that is timely as well for those of us engaged by the immediate problems of a busy practice.[1] He told these young lawyers that, in the final analysis, the most satisfactory part of a law practice is the quest for justice—not merely the attainment of skill as a technician in the law. He recognized that it is not always easy to follow the trail in a "distant and nebulous quest for justice." The truth of the latter statement is borne out by the fact that no less than three papers on the subject of restitution have appeared in the FOOD DRUG COSMETIC LAW JOURNAL,[2] and the subject has been discussed in both the Stanford [3] and Harvard law reviews.[4]

Actually, my talk today might well be entitled "Justice," for restitution is only a way of doing elementary justice. It needs no present-

[1] Wilson, "A Knight in Shiny Blue Serge: Advice to Young Lawyers," 40 *American Bar Association Journal* 686 (August, 1954).

[2] Levine, "Restitution—A New Enforcement Sanction," 6 FOOD DRUG COSMETIC LAW JOURNAL 503 (1951); Noland, "Section 302(a) of the Federal Food, Drug, and Cosmetic Act: Restitution Re-examined," 7 FOOD DRUG COSMETIC LAW JOURNAL 373 (1952); and Rhyne, "Penalty Through Publicity: FDA's Restitution Gambit," 7 FOOD DRUG COSMETIC LAW JOURNAL 666 (1952).

[3] "Restitution in Food and Drug Enforcement," 4 *Stanford Law Review* 519 (1952).

[4] "Developments in the Law—The Federal Food, Drug, and Cosmetic Act," 67 *Harvard Law Review* 632, 718-720 (1954).

The Author Is Assistant General Counsel, United States Department of Health, Education, and Welfare

day apologist to gain admission into prayers for relief in either federal or state courts.

Historically, the principle was stated by Pomponius as far back as the second century as follows: "For this by nature is equitable, that no one be made richer through another's loss." [5] The modern restatement is: "A person who has been unjustly enriched at the expense of another is required to make restitution to that other." [6]

Indeed, the American Law Institute devoted one of its earliest restatements of the law to restitution, collecting principles founded in quasi-contract, unjust enrichment, constructive trusts and the general equity jurisdiction on which restitution rests. Recognition of the scope and significance of restitution as a distinct remedy "which pervades the whole of the law" has been one of the real developments of the last 20 years.[7]

Plainly, under the accepted principles of justice by which we live, a person deprived of money through a sale of merchandise induced by fraud and made illegal by Act of Congress is seeking no new, unusual, far-reaching or unheard-of relief when he asks that the illegal transaction be set aside and his money restored to him.

The question of particular concern here is whether restitution may be ordered in a suit for statutory injunction brought by the United States under the Federal Food, Drug, and Cosmetic Act; whether the government may vindicate private rights in its injunction suit. If it

[5] "Restitution—A Search for a Philosophy," 6 *Journal of Legal Education* 330 (1954).

[6] Restatement of the Law of Restitution, Sec. 1.

[7] Book Review, *Cases on Quasi-Contract*, 5 *Journal of Legal Education* 242-244 (1952).

may not—and I do not concede that it may not—we must accept as a part of our interstate distributional system the predatory entrepreneur who executes a get-rich-quick scheme of relieving thousands of our citizens of relatively small individual sums of money through fraudulent promises as to the great curative or restorative powers of his own particular nostrum. We must accept the type of individual who preys on man's desire for a longer or more satisfactory sex life or, worse, we must accept the individual who provides soothing, but illusory, promises of cure to frantic relatives of the unfortunate victims of incurable disease.

On experience alone, it is established that criminal penalties are of little concern to the "one-shot" operator. The chances of jail sentence are remote. Even a fine substantial by comparison with other fines for food and drug violations leaves the operator with almost all of the loot he has gathered in thousands of small increments from his mail-order customers.

Seizure is out of the question as an adequate remedy. Even if a multiple-seizure campaign were promptly launched and vigorously prosecuted, it would overwhelm the federal courts to arrest completely a nation-wide distribution of a worthless drug sold on mail order. Post Office and Federal Trade Commission orders require considerable time before they may be obtained and executed.

Only the statutory injunction seems to offer a means of promptly drying up the stream of illicit merchandise. But even the injunction usually can be obtained only after the scheme of distribution has been placed in operation, customers located, samples collected and evidence readied for the legal struggle. Meanwhile, the flow of orders—and checks—ordinarily will have reached sizable proportions, especially if the fraudulent scheme is a clever one.

Recently, we encountered just such a clever scheme. Fortunately, it was nipped in its early budding but, even so, the orders had reached the 500-a-day mark.

The get-rich-quick scheme was quite interesting. The individuals involved had been convicted in a criminal case and placed under a permanent injunction a few years ago, as a result of direct-mail selling of methyl-testosterone, which, they promised, offered a new lease on sex life to men over 40.[8] Methyl-testosterone is an extremely dangerous drug for unsupervised use by the public.

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[8] See *U. S. v. El-O-Pathic Pharmacy, et al.*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7206, 192 F. (2d) 62 (CA-9, 1951).

The new scheme revolved around a harmless tablet comprised of thiamine, vitamin C, niacin, calcium pantothenate, vitamin B_{12}, caffein, potassium and molybdenum, in a base of wheat germ oil and inert testicular materials. According to the labels, the tablets came in two strengths, "standard" and "super." Actually, the tablets were all the same. One simply took four tablets a day from the bottle labeled "super" instead of two from the standard prescription.

The promotional scheme was ingeniously devised. The promoters prepared and had printed, in Los Angeles, an envelope, sales letter, sales circular, order form and business-reply envelope. Type and color were selected to simulate German print. A fanciful name was chosen of a company purportedly in Frankfurt am Main, Germany. A slogan in German and a coat of arms were printed on the material. Even a street address and bank reference in Frankfurt were given. An advertising and sales office address in London was included, as was a list of European sales offices.

The sales letter announced the product as a "new and original German formula" which would perform miracles for the sex life of all males. It was offered with a guarantee of satisfaction within 24 hours, or a refund of money. The letter was signed with a name corresponding to that of the purported company. The air-mail business reply envelope was addressed to a company at Long Beach, California, said to be the American agents of the German firm under a licensed agreement.

Tens of thousands of the promotional letters, preaddressed to persons on the Long Beach company's mailing list, were sent in bulk packages from Los Angeles to London. There they were postmarked and the English stamps cancelled, and then sent back to the United States in groups of 1,000 for mail distribution to potential customers.

Hopeful males by the thousands began sending in their money for the "new and amazing miracle"—from $10 for the one-month trial of the "standard" to $35 for three months' supply of the "super." The material cost the distributor approximately 25 cents a bottle.

Actually, the "scientist" for whom the German "company" was named, pictured in the promotional material, was a professional model who had lived in Hollywood 13 years earlier, when the photograph was taken.

There was no German firm by that name, nor was there a London office. Our inquiry through the State Department developed that the

Frankfurt address was occupied by a firm of publishers, who had never heard of the purported company. The London address had never been occupied by such a firm.

Armed with this information, together with medical proof of the utter worthlessness of the drug as a sex rejuvenator, we sought and obtained a temporary restraining order—and later a preliminary injunction—which applied the legal brakes about 20 days after the first promotional material was distributed nation-wide.[9] We had learned of the scheme on February 3. The first deliveries of the drug had reached the distributor on February 19. On February 26, the temporary restraining order was entered.

Would justice be served by permitting this promoter to retain the riches he unjustly obtained through his fraudulent promises? We didn't think so then, and we don't think so now—so the complaint for a permanent injunction included a prayer for restitution. But the prayer for restitution is yet to be heard.

Legal Basis for Restitution

Is there a sound legal basis for such relief? We think so.

The theory behind it was first advanced in the *Mytinger & Casselberry* litigation in the Southern District of California.[10] The firm moved to strike the prayer from the complaint, but the motion was denied after the district court heard the arguments. The consent decree was signed before the matter was litigated further.

Very briefly, the prayer is based on the contention that Congress, in granting the district courts jurisdiction to restrain violations of the Federal Food, Drug, and Cosmetic Act, granted them full powers to decree all necessary equitable relief not only to prohibit the unlawful conduct for the future, but also to require the defendant to disgorge his unlawful gains and, as much as is practicable, to restore the *status quo*. The purpose is to prevent future violations and "to undo what could have been prevented had the defendants not outdistanced the Government in their unlawful project." [11]

A leading case, of course, is *Porter v. Warner Holding Company*, 328 U. S. 395 (1946). The Supreme Court there held that when the

[9] *U. S. v. Wayne A. Parkinson, et al.*, Dkt. No. 16415-C (DC Calif., 1954).

[10] *U. S. v. Mytinger & Casselberry, Inc., et al.*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7203, No. 10344-BH (DC Calif., 1951).

[11] *U. S. v. Schine Chain Theatres*, 1948-1949 CCH TRADE CASES ¶ 62,245, 334 U. S. 110.

Administrator of the Office of Price Administration invoked the jurisdiction of the district court to enjoin acts and practices made illegal by act and to enforce compliance, the jurisdiction was an equitable one, and that, unless provided otherwise by express language or by necessary inference from the statute, all the inherent equitable powers of the district court were available for the proper and complete exercise of that jurisdiction. Since the public interest was involved, the equitable powers assumed an even broader and more flexible character than would exist if only a private controversy were at stake. The district court, in exercising this jurisdiction, had full power to do equity and to mold a decree to the necessities of the particular case.

Said the Court:

> It is readily apparent . . . that a decree compelling one to disgorge profits, rents or property acquired in violation of [the Act] . . . may properly be entered by a District Court once its equity jurisdiction has been invoked under § 205(a).

Attempts to Explain Away *Warner* Case

Mr. Charles S. Rhyne and Mr. John Philip Noland, Jr., have attempted to explain this case away, insofar as the food and drugs Act is concerned, by pointing out that the statutory language is different and that the rent control act authorized the district courts to enjoin violations, to compel compliance and to issue "other orders." They argue that the Supreme Court based its decision on the authority granted to issue "other orders." Plainly, the decision cannot be so limited, for if this were so, the discussion of equity powers and the full scope of equity jurisdiction would have been beside the point. The decision might have been made to turn solely on a matter of statutory construction. But it was not.

The subsequent case of *U. S. v. Moore*, 340 U. S. 616 (1951), where the court held that restitution could be granted without an application for an injunction on the grounds that it was an "other order" necessary to enforce compliance with the statute, merely indicates that that particular statute provided some remedies in addition to traditional equity relief. This in no way detracts from the reasoning of the court in the *Warner Company* case to the effect that the traditional equity powers appealed to by an application for an injunction are sufficient to provide the basis for issuance of a decree ordering restitution as an equitable adjunct to an injunction decree.

Even more directly applicable are the wage-and-hour cases in which restitution has been ordered as an adjunct to the statutory

injunction. That statute became law the very same day the Federal Food, Drug, and Cosmetic Act was enacted. Its language conferring jurisdiction to grant statutory injunctions is identical with that of the Federal Food, Drug, and Cosmetic Act. Under the wage-and-hour law, the United States Court of Appeals for the Second Circuit, in *U. S. v. Frank Scerbo & Sons,* 177 F. (2d) 137 (1949), held that the power "to restrain violations" included power to order restitution of wages unlawfully withheld before the entry of the injunction. The court reasoned that when the Administrator invoked the injunction process in the public interest, the court had the traditional power of an equity court to grant full relief, including restitution or reparation where necessary. The statute involved had no provision expressly authorizing "other orders."

Mr. Noland has made a grand effort to explain all the wage-and-hour cases away.[12] He explains the entire doctrine as a grotesque judicial mistake. It arose, he has said, from the "almost tortuous reasoning" of Judge Woodrough of the Eighth Circuit. Judge Hincks, now on the Second Circuit, was "confused" by Judge Woodrough and delivered an opinion which Mr. Noland dismisses as "rudderless meanderings." The crowning blow fell when Judge Hand "blundered," and followed the Woodrough reasoning. Judge Frank followed the false trail with *Scerbo.*[13]

But the Eighth and Second Circuits were not the only circuits that became "confused," according to Mr. Noland. The Fourth, Fifth and Ninth Circuits, all of which approved the restitution doctrine, are said to have "carelessly" read the Supreme Court's decision in an earlier case.[14] The only court that properly analyzed the legal problem was a Georgia district court![15] Its opinion on the point, Mr. Noland says, is a dictum.

The wage-and-hour cases are not readily swept aside. But solace is found by some in that Congress amended the wage-and-hour law to "overrule" the *Scerbo* doctrine. The significance of this fades when the amendatory statute is examined. What Congress actually did was replace the *Scerbo* doctrine by granting the government a plain statutory right to sue for damages on behalf of wage earners.[16] This changed the equitable remedy into a legal right.

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[12] Noland, work cited, at pp. 379-385.
[13] Noland, work cited, at pp. 380-383.
[14] Noland, work cited, at pp. 383-385.
[15] Noland, work cited, at p. 386.
[16] 29 USC Sec. 216(c), and see H. Rept. 1453, 81st Cong., 1st Sess. (1949).

Still further support for our contention may be found in the anti-trust cases where divestiture has been ordered. In the *Schine Chain Theatres* (cited above) and *Paramount Pictures* (1948-1949 CCH TRADE CASES ¶ 62,244, 334 U. S. 131) cases, the Supreme Court said (in *Schine*):

> In this type of case we start from the premise that an injunction against future violations is not adequate to protect the public interest. . . . They could retain the full dividends of their monopolistic practices and profit from the unlawful restraints of trade which they had inflicted on competitors. . . .
>
> To require divestiture of theatres unlawfully acquired is not to add to the penalties that Congress has provided in the antitrust laws. Like restitution it merely deprives a defendant of the gains from his wrongful conduct. It is an equitable remedy designed in the public interest to undo what could have been prevented had the defendants not outdistanced the government in their unlawful project.

Again discussing divestiture (in *Paramount*) as a part of its decree, the Court said:

> Otherwise, there would be reward from the conspiracy through retention of its fruits. Hence the problem of the District Court does not end with enjoining continuance of the unlawful restraints nor with dissolving the combination which launched the conspiracy. Its function includes undoing what the conspiracy achieved. As we have discussed in *Schine Chain Theatres, Inc. v. United States*, 334 U. S. 110, 68 S. Ct. 947, the requirement that the defendants restore what they unlawfully obtained is no more punishment than the familiar remedy of restitution.

See also *Deckert v. Independence Shares Corporation*, 311 U. S. 282, 289 (1940); and *U. S. v. United States Gypsum Company*, 1950-1951 CCH TRADE CASES ¶ 62,729, 340 U. S. 76 (1951).

These cases wholly answer the claim that restitution, if ordered, would be an addition to powers granted by Congress.

Conclusion

The reputable and honest businessman need have no fear of restitution as a remedy. He conducts his daily operations under rules of law that subject him to a private suit for restitution if he is unjustly enriched. Any order for restitution as an adjunct to the statutory injunction would be based on principles of justice as old as law itself. Such an order would vindicate private rights which presently are beyond self-protection because of the relatively small individual claims involved and the distance between the person who has been defrauded and the one responsible for the fraud.

We do not know whether the remedy will be held available to the government. But we are convinced that justice would be served by restoring money unlawfully obtained to its rightful owners. **[The End]**

A Report from England

By CHARLES A. ADAMS, C. B. E.

This Is the Text of a Paper Read for the Author at the Annual Meeting of the Division of Food, Drug and Cosmetic Law in the Section of Corporation, Banking and Business Law of the American Bar Association at Northwestern University, Chicago, Illinois, on August 17, 1954

WHEN YOUR CHAIRMAN invited me to contribute a paper from England, I readily agreed because though I knew that my good friends William Goodrich of Washington, D. C., and R. E. Curran of Ottawa, Canada, would have the advantage and pleasure of addressing you in person, nevertheless I was confident at that date that I would have something definite in legislation to report. In this I have been unlucky, for the progress of the food and drugs amendment bill through Parliament has been disappointingly slow, and at the date of writing (July 23, 1954) we still await its final approval by the legislature.

Wartime Controls

When last I had the privilege of addressing this important assembly, it was my pleasure to indicate the steps which had been taken in the United Kingdom to strengthen our food legislation—steps which brought it more into line with that of the United States and Canada. Wartime shortages of food, coupled with a regretable increase in the adulteration of foods and in the passing off of inferior products by a fringe of less reputable traders, made it imperative for the government to introduce more stringent legislative controls for the protection of the consumer.

The Defence (Sale of Food) Regulations of 1943, supplemented by the labeling-of-food orders and the food-standards orders made under the powers given by those regulations, have resulted in a significant volume of positive legislative controls in the decade which has followed. But the urgency of wartime controls has now passed.

Mr. Adams Is Past Director, United Kingdom Food Standards and Labelling Division

Value to Consumer Calls for Permanence

Though Parliament has seen fit to renew this "emergency" legislation from year to year, this is no longer a satisfactory state of affairs for controls which have proved of permanent value. One of the primary purposes of the food and drugs amendment bill is to enshrine these controls in permanent legislation.

Perhaps I should explain, in passing, that this bill was introduced by the government some six months ago as a noncontentious measure, agreeable in principle to all parties. It was, therefore, possible to reverse the normal procedure applying to contentious measures and to take advantage of the lesser pressure of business in the House of Lords, and introduce it there rather than in the House of Commons.

Measure Has Passed Through House of Lords

As of today the bill has been through all its stages in the upper house and now awaits a lull in the legislative program of the Commons so that it may be considered there. Until it has been passed by both houses it cannot, of course, become law. It might be added that the bill had a smooth passage in the Lords, and few amendments of consequence were debated. It would be unwise to prophesy that the same will obtain in the Commons, though it may well be so. Nevertheless, it is not yet possible to comment on the measure as one which has found a place on the statute book.

The discussion has, so far, been by way of introduction. What, you may ask, does the bill set out to do? On its introduction, it was welcomed on all sides as a desirable "pure foods bill," and this description was widely adopted for it in the press.

Bill Deals With Many Topics

I should make it clear at once, however, that only some half-dozen clauses deal with and amend the law covering the composition, labeling and advertising of food and drugs, for the major part of the bill deals with the allied topics of the sale of unsound food, of the control of slaughterhouses, of food hygiene and food poisoning, and of the necessary provisions for sampling, analysis, inspection of premises, penalties and enforcement. In its over-all pattern, therefore, the bill follows that of the current food and drugs act of 1938, which is only to be expected in an amending measure.

I will deal only with the provisions falling within the first category mentioned above, though it may be worth remarking that in view of the preponderance of clauses dealing with the other topics, the measure is now more commonly referred to as a "clean food" bill. In effect, it is both, and it seems preferable that the emphasis remain on purity rather than on cleanliness, so that these very important attributes may be given their logical priorities.

Provisions Relating to Composition

The opening clause of the bill deals with the protection of the consumer from health hazards which might follow the ingestion of food containing chemical additives. This clause makes it an offense to add anything to a food which will render that food injurious to health. At this point, the provision appears to be little different from Section 1 of the 1938 act, which has always suffered, in practice, from the defect of the extreme difficulty of proving in law that an alleged injury to health has been caused by a chemical additive, especially when such injury may follow the ingestion of the food only over very long periods of time. In an endeavor to remedy this defect in the current law, Clause 1(5) of the bill now states that:

> . . . in determining . . . whether an article of food is injurious to health, regard shall be had not only to the probable effect of that article on the health of a person consuming it but also on the probable cumulative effect of articles of substantially the same composition on the health of a person consuming such articles in ordinary quantities.

Just how far this will prove capable of improving the position of enforcing authorities remains to be seen, but the provision may be accepted as a constructive attempt to deal with the difficulties which have confronted the authorities when all the circumstances of a case

and the evidence available have been in the direction of indicating *chronic* rather than *acute* poisoning.

The bill also extends the regulation-making powers given originally by the 1938 act. It would be premature to go into these in detail pending the passing of the measure, but it is of interest to notice one entirely new provision (Clause 4) to the effect that "in the interests of public health, or otherwise for the protection of the public," the addition to food of either a "specified substance or class of substance" can be prohibited or regulated, as can the use of any process or treatment in food manufacture. In particular, the Minister is directed to have regard to "the desirability of restricting, so far as is practicable, the use of substances of no nutritional value as foods or as ingredients of foods." Parenthetically, it is to be remarked that this principle has been applied in the recent standards order for saccharin tablets, which in effect prohibits the sale of tablets, for use in foods, containing synthetic sweetening agents other than saccharin.

Information Requirement

This control of the use of chemicals in food is dealt with in a somewhat novel way by providing that the appropriate minister may, by order, ask to be furnished with particulars of the use of substances of any class specified in such order (for example, fat extenders, antioxidants), and of their chemical composition, the manner of their use, and particulars of investigations pointing to their safety.

Obviously, there is no banning of the use of new chemicals here, but it would appear that the authorities will be in a position to be kept informed of groups of substances going into food manufacture should they deem such information advisable. This, supported by the power to control such use by regulation as mentioned above, should go some distance towards finding a workable solution to this very difficult problem.

Food Labeling and Advertisements

The wartime powers relating to food standards and food labeling will, of course, be re-enacted by the bill so that they may now find a place in permanent legislation. There is, too, an important addition to these powers, namely, a new power to regulate food advertisements which hitherto had no place in the United Kingdom law. This is a most important advance, and its wise administration should bring wide benefits to consumers and food manufacturers alike.

Such, in briefest outline, is the design of the bill as it goes to the Commons. At the moment, the position is one of suspended animation, and, a final assessment must await the deliberations of the House of Commons prior to the bill's receiving the royal assent.

Progress of Food-Standards Committee

Let us, therefore, look for a few moments at the progress which has been made under current legislation during and since the war years. The Food and Drugs Act of 1938, supplemented by the Defence (Sale of Food) Regulations of 1943, saw the beginning of a program of food-standards orders. In these developments the Minister of Food is assisted by a permanent Food Standards Committee under the chairmanship of his chief scientific adviser. Legal standards have now been prescribed for some 20 foods, while about a dozen other cases are under examination by the committee (see Appendix). In addition, this committee has appointed two subcommittees to report to it on (1) the presence of trace elements in foods and (2) the revision, so far as may be necessary, of the Preservatives in Food Regulations of 1925. The former, the Metallic Elements Sub-committee, has already issued reports on the occurrence in food of arsenic, lead, copper, zinc and tin, and has recommended tolerances covering these elements for the prevention of danger to health. The Preservatives Sub-committee has issued a report on the use of antioxidants in food manufacture, which includes recommendations for their use and control. An important report on the use of coloring matters in food is in active preparation. It is only to be expected that some, at any rate, of these recommendations will be the subject of future controls. On the use of toxic chemicals in agriculture, notice should be taken of the 1951 report of the working party under Professor Zuckerman, in which recommendations were made for the promotion of the safety of workers in their handling of toxic chemicals and application of them to crops. Following the publication of this report, the working party was reappointed to inquire into the matter of whether the consumer of vegetable products which have been so treated is subject to any health hazard. In the result, a further report on toxic residues in agricultural products was published last year. (Both reports can be obtained from Her Majesty's Stationery Office.)

This record of progress, which has been given in the barest outline, is presented to you as an important and constructive contribu-

tion to the problems which modern chemistry presents to the legislature and to food producers today, and on these grounds I am sure it will be welcomed by The Food Law Institute.

Merchandise Marks Act

In conclusion, I feel your attention should be called to one more statute, which came into force last February, namely, the Merchandise Marks Act. Though this measure is designed to apply to goods generally, its effects may well be felt to a considerable degree in the field of foods and drugs. The parent act of 1887 made it an offense to apply a false "trade description" to any goods, but this term was so defined in the act that the provision could be operated only in a restricted manner. In these days of substitute materials, on the one hand, and of modern advertising methods, on the other, wider powers had long been called for. The new act aims to meet these requirements by broadening the definition applying to false trade descriptions, in particular by extending it to include statements which, though they may be true as a whole, nevertheless are likely to mislead a purchaser. The result appears to come very near to the long-established doctrine applying to false and misleading claims in the Food and Drugs Act. But whereas that Act is enforced by local food and drugs authorities, the Merchandise Marks Act is open to procedure by a common informer. The old doctrine of *caveat emptor* seems now to be outmoded, and a new one of *caveat vendor* may soon be nearer the truth. This is a significant change, indeed.

Concluding this report, may I thank you for giving me this opportunity of keeping in touch with The Food Law Institute? Also may I convey my sincere thanks for the reading of my paper? **[The End]**

Appendix

Foods for which standards of composition have been prescribed include: baking powder and golden raising powder, liquid coffee essence, mustard, salad cream and mayonnaise, self raising flour, coffee mixtures, cream, curry powder, edible gelatin, fish cakes, fish paste, ice cream, margarine (vitaminization), meat paste, preserves (including mincemeat and fruit curd), saccharin tablets, soft drinks, suet, table jellies, and tomato ketchup.

During the Public Conference on the Food and Drug Law Held in Los Angeles on May 15, 1954, the Writer Showed the Importance of

California's Part in Food and Drug Law

By WAYNE D. HUDSON

THE TERM "food and drug law" refers, when used in a general way, to an undefined host of laws, both state and federal. These laws are of the greatest social and economic importance. Dealing, as they do, with the entire course of the production, manufacture and distribution of foods and drugs, they touch the lives of the entire public and influence a larger segment of commerce than any other body of laws.

The emphasis of most conferences such as this is, properly, upon the federal legislation dealing with the subject. The states, however, play an important part in the surveillance of this commerce. California has a great many special laws relating to foods and drugs, and has a general pure foods act[1] and a pure drugs act.[2] We take pride in the claim that, among the states, we are excelled neither in the quality of our food and drug laws nor in the quality of their enforcement. The fact that we can justly make this claim is due, in large measure, to the efforts of Milton P. Duffy, Chief of the Bureau of Food and Drug Inspection.

The California Pure Foods Act and California Pure Drugs Act are general regulatory statutes which proscribe the misbranding, false advertising or adulteration of food or drugs. These statutes are modeled after the Federal Food, Drug, and Cosmetic Act of 1938.[3]

The federal Act rests, of course, upon the power of Congress to regulate interstate commerce. The substantive provisions of the

[1] California Health and Safety Code, Secs. 26450-26624.

[2] California Health and Safety Code, Secs. 26200-26385.

[3] 21 USC Secs. 321, and following.

Mr. Hudson, Who First Taught Undergraduate Food-Drug Law at Stanford University, Is Deputy Attorney General of California

federal Act cannot attach to an article of food or drug until the product becomes an article of interstate commerce or an article affecting interstate commerce. The state acts, on the other hand, are not subject to any such power limitation. The legislature, within the bounds of due process, may deal with misbranded and adulterated food and drugs whenever and wherever they exist within the geographical limits of the state.

The importance of the jurisdictional difference between the federal Act and the state acts is well illustrated by a problem with which the California Attorney General is now confronted. The attorney general's opinion has been requested on the following question:

> Is fruit which is cut and dried on the grower's ranch and intended for sale to others for further processing, subject, while still in the hands of the grower, to the provisions of the California Pure Foods Act?

Dried fruit is an important product of the extensive fruit industry existing in this state. Prunes, apricots, peaches, apples, grapes, figs and other fruits lend themselves to marketing in dehydrated form. Within the dried-fruit industry, it is the practice for much of the actual drying of the fruit to be done by the grower on his own premises. This drying is ordinarily accomplished by cutting the fruit to a desired size and spreading it in the open where it is subject to the movement of the air and the direct rays of the sun. Under these conditions a natural dessication takes place. The fresh fruit used for drying on the farm is, in the usual case, orchard-run material—that is to say, the fruit used is that taken from the trees without sorting or grading, or other processing of this kind.

The resulting dried product is not sold by the grower to the consumer nor for direct distribution to the consumer's market. Rather, it is sold to industrial agencies for further processing. The establishments receiving the orchard-run material process the dried fruit through sorting, grading, cleaning and packing. It is then distributed to the wholesale and retail trade.

The question presented is whether fruit—during or after the drying process, but before shipment by the grower—is subject to the provisions of the pure foods act. In discussing this question, I must emphasize that the views expressed are my own and are not official. The consummate opinion of the office of the attorney general has not yet been formulated.

Three arguments are presented which contend against the inclusion of such fruit within the scope of the act. It is said that since the fruit is incompletely processed—since it is still to be sorted, graded and cleaned before being sold for consumption—it is not yet "food" within the meaning of the act. Second, it is contended that standards prescribed in the agricultural code pre-empt the jurisdiction over farm produce. Third, it is said that the legislature did not intend to invade the private domain of the farm, and that the provisions of the act do not apply to food until the food has left the farm and actually entered the channels of commerce. My conclusion is that none of these contentions can be sustained.

Definition of "Food"

The term "food" is defined by the state act as follows:[4]

> "Food" includes all articles used for food, drink, liquor, confectionery, condiment or chewing gum by man or other animals, whether such articles are simple, mixed, or compound.

The above definition is essentially the same as that contained in the Federal Food, Drug, and Cosmetic Act.[5] Cases under the federal Act dealing with the matter are instructive.

U. S. v. 52 Drums of Maple Syrup[6] involved condemnation proceedings against a quantity of maple syrup. The syrup had been shipped by the owner, in interstate commerce, to the owner's processing plant where it was to be used as raw material. The material shipped had been reduced from maple sap by evaporation. In the process of evaporation the syrup had become adulterated with a quan-

[4] California Health and Safety Code, Sec. 26450.

[5] 21 USC Sec. 321(f).

[6] 110 F. (2d) 914 (CCA-2, 1940).

tity of poisonous lead in excess of the established tolerance therefor. Agents of the federal Food and Drug Administration seized the shipment. In the forfeiture proceedings that followed, the owner contended that the federal Act did not apply since the syrup was incompletely processed and would be made pure by further processing before being sold or otherwise disposed of. The court said that this was a wholly false issue. The owner's intention with respect to an adulterated food was held to be immaterial on the question of the government's right of seizure.

Three Appeals Consolidated

U. S. v. O. F. Bayer and Company [7] was a consolidated appeal from three suits for the condemnation of quantities of green coffee beans. The green coffee beans had become contaminated with dirt, wood splinters and other adulterants. Two of the district courts had ordered condemnation; the third had dismissed the libel. The dismissal was predicated on findings (1) that green coffee beans were not food and (2) that there was no evidence that the customary and necessary process to which green coffee beans intended for human consumption are subjected would not render this seized material wholesome.

On appeal the judgments of condemnation were affirmed; the judgment of dismissal was reversed. The court held that green coffee beans are food. It is immaterial, the court said, that a further process such as roasting is necessary before the beans are intended for human consumption. A food does not have to be ready to eat or drink before it can be adulterated and, thus, subject to seizure and condemnation. Further, a food which is adulterated may be condemned even though it is intended that the adulteration be eliminated by a future process.

The above cases and others appear to have concluded the issue insofar as the federal Act is concerned.[8] These cases should be endorsed and accepted in the interpretation of the state act. It would follow that incompletely processed fruit is "food" within the meaning of the statute.

The second issue is whether the legislature has displaced the pure foods act with a specific statute dealing with the particular commodi-

[7] 188 F. (2d) 555 (CA-2, 1951).

[8] *Otis McAllister & Company v. U. S.*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 9223, 194 F. (2d) 386 (CA-5, 1952); *U. S. v. 11¼ Cans Containing Butter*, 148 F. (2d) 365 (CCA-5, 1945); *Union Dairy Company v. U. S.*, 250 F. 231 (CCA-7, 1918).

ties in question. The fruit, nut and vegetable standards of the agricultural code constitute legislative quality and packing standards for farm produce.

These quality standards have to do with such factors as the presence of worms, mold and decay; insect injury; maturity; and so forth. Such factors relate solely to defects which subtract from the excellence of the product as such. They do not purport to regulate the wholesomeness of a commodity, and offer no protection to the public in this regard.[9] It is thus apparent that the agricultural standards are not exclusive quality requirements.

The standards of the agricultural code and the requirements of the pure foods act do not conflict. One is complementary to the other, and they may be consistently so applied. The legislative scheme seems apparent. For example, dried fruit which contains an excessive amount of insecticide does not violate the agricultural standard. It does violate the health requirements of the pure foods act.[9] Dried fruit which has been processed under insanitary conditions does not violate the agricultural standard. It does violate the health requirements of the pure foods act.[10] Fruit which might otherwise be deemed adulterated under the pure foods act because of the presence of mold or decay is not so adulterated if the defection falls within the limits of a standard specifically established by the legislature among the fruit, nut and vegetable standards of the agricultural code.

The third issue is whether enforcement of the California Pure Foods Act extends to food which is still in the hands of the producer and has not yet entered commerce. A ready answer is provided by the statute.

California Code—Pertinent Provisions

Relevant sections of the California Health and Safety Code provide as follows:

§ 26510. . . . The manufacture, production, preparation, compounding, packing, selling, offering for sale or keeping for sale, or advertising within the State of California, or the introduction into this State from any other State, Territory, or the District of Columbia or from any foreign country, of any article of food which is adulterated or misbranded is prohibited. . . .

§ 26518. . . . The possession, sale, or offering for sale of any adulterated or misbranded article of food by any manufacturer, producer, jobber, packer, or

[9] California Health and Safety Code, Sec. 26470(1)-(2).

[10] California Health and Safety Code, Sec. 26470(4).

dealer in food, or broker, commission merchant, agent, employee, or servant of any such manufacturer, producer, jobber, packer, or dealer, shall be prima facie evidence of the violation of this chapter. . . .

§ 26459. . . . The provisions of this chapter regarding the selling of food, shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession, and holding of any such article for sale; the sale, dispensing, and giving of any such article; and the supplying or applying of any such articles in the conduct of any food establishment.

It seems clear that the fruit in question is produced, prepared and kept for sale within the literal wording of Section 26510. The fruit is in the possession of the producer within the literal wording of Section 26518. It is produced, processed and held for sale within the literal wording of Section 26459. These sections seem to admit of no construction beyond the plain meaning of the language used.

Construction of Statute Must Protect Public

Were there room for construction, regard should be had to the evils which called forth the statute, and a construction should be adopted which gives it an effect in accordance with its design and purpose. The California Pure Foods Act is a remedial statute intended to protect the public health and pocketbook, and it should be liberally construed in order to provide an effective instrument of law.[11]

Let us suppose a quantity of dried fruit is in the hands of a producer. Suppose further that the fruit, while on the trees, had been sprayed with an excessive amount of insecticide, so as to render the fruit a menace to health. This fruit would be adulterated within the provisions of the act.[12] If the public is to be protected from such food, it is not sufficient that anyone who sells the fruit is subject to a criminal penalty.[13] Effective enforcement requires access to the farm to discover the fact of adulteration and seizure at the farm to prevent the food's entering commerce. Otherwise the food may be spread to widely divergent places before the fact of adulteration is discovered, and it may be in the hands of consumers before seizure can remove it from the market.

When Wholesome Food Becomes Contraband

Suppose that the raw fruit is wholesome, but is being dried under insanitary conditions. The fruit would be adulterated within the pro-

[11] *U. S. v. Dotterweich*, 320 U. S. 277 (1943); *U. S. v. Antikamnia Chemical Company*, 231 U. S. 654 (1914).

[12] See footnote 9.

[13] California Health and Safety Code, Sec. 26519.

visions of the act.[14] It is in the public interest that such conditions be abated. The pure foods act is the only effective means of regulation provided.

All articles not intended for consumption by the producer are designed for sale and it is, therefore, the concern of the law to have them pure.[15] If food is clean and wholesome, it has unimpeded recourse to the market. If food is adulterated, it is subject to the circumspection provided by the statute. Adulterated food is contraband that is subject to seizure.[16] Criminal penalties may be imposed.[17] The legislation is of a now-familiar type whereby penalties serve as effective means of regulation. In the interest of the larger good, the statute puts the burden upon the person who stands in a responsible relation to the public danger.[18]

A farmer may become possessed of adulterated food because of circumstances quite beyond his control. Further, when a food becomes adulterated the producer in possession may no longer hold the article for sale as food but may intend other disposition. The chance that such food may be seized by the state and the possessor subjected to a criminal penalty arouses a sense of injustice. It is important, therefore, that the legislative scheme be viewed comprehensively.

Seizure Procedure

Seizure under the act does not mean summary dispossession and destruction. Whenever an authorized agent has probable cause to believe that food is adulterated, he may detain such food by appropriate marking and notice.[19] The food cannot thereafter be moved or disposed of without the permission of the agent or a court of competent jurisdiction. After appropriate findings by the administrative agency the food may actually be seized.[20] Court proceedings must then be instituted seeking the condemnation of the food. The owner of the goods may appear in the action and defend against the charge of adulteration.[21] He may himself institute the proceedings if the

[14] See footnote 10.
[15] *Hipolite Egg Company v. U. S.*, 220 U. S. 45 (1911).
[16] California Health and Safety Code, Secs. 26580-26590.
[17] California Health and Safety Code, Sec. 26519.
[18] *U. S. v. Dotterweich*, cited at footnote 11.
[19] California Health and Safety Code, Sec. 26580.
[20] California Health and Safety Code, Sec. 26581.
[21] California Health and Safety Code, Sec. 26586.

agency is dilatory in so doing.[22] If the food is adjudicated as adulterated the court will issue its decree of condemnation.[23]

At any time before the entry of a court decree, the Bureau of Food and Drug Inspections is authorized to release the food from detention.[24] In the vast majority of cases, the offending conditions are voluntarily corrected to the satisfaction of the bureau. Under the supervision of the bureau, adulterated food is voluntarily rectified or disposed of in some harmless way. Even after condemnation of the food by a court, the ensuing decree may allow correction of the adulteration or disposal for such use as may be deemed fit.[25] This latter procedure, however, requires the posting of a bond conditioned upon the seized goods' not being sold in violation of the act.[26]

The seizure sanction of the act does not, therefore, place an unreasonable or unjust burden upon producers. Rather, it is an aid to the honest and well-intentioned producer, for it relieves him of competition by those who would exercise the privilege of producing and selling food for public consumption without undertaking the safeguards necessary to the public.

The possibility of an unjust criminal penalty remains. It should suffice to say that before the Bureau of Food and Drug Inspections may institute a criminal action, the concurrence of the district attorney—and perhaps of the attorney general—is required. The judgment of a court stands between the institution of such a suit and a conviction. These safeguards against arbitrary action are adequate. The possibility of injustice is remote.

Food and drug legislation, whether state or federal, is corrective legislation, both in intent and in fact. The true measure of its success is the measure of corrective influence which is realized. Such corrective influence is exercised by sympathetic, constructive work with the food and drug industry. The penal aspect of the legislation is a matter of necessity. It lends authority to the expert agency charged with enforcement. Everyone is familiar with reading, writing and arithmetic, taught to the tune of a hickory stick. We are here dealing with the integrity of foods and drugs, taught to the tune of judicial power.

[The End]

[22] California Health and Safety Code, Sec. 26586.5.

[23] California Health and Safety Code, Sec. 26587.

[24] California Health and Safety Code, Secs. 26580, 26582, 26589.5.

[25] California Health and Safety Code, Sec. 26588.

[26] California Health and Safety Code, Secs. 26588-26589.5.

The Chemical-Additive Amendment

TO THE 1938 FEDERAL FOOD, DRUG, AND COSMETIC ACT

By R. C. NEWTON

The Author Tells the August 17 ABA Meeting That Public Interest Demands That Any Revision of the Law Decisively State Requirements for Securing Approval of Use of New Chemical Substances in Foods

THE PROBLEM of chemicals in food is not new, but the accelerated pace of the application of chemicals in food production and processing has increased the hazard of serious error, and thus accentuated public interest in the subject. We should not spend time in this meeting trying to define precisely the word "chemical," but should consider our problem in terms of those substances which, because of character or amount, may interfere with the physiological processes of the human body.

It makes no difference to our bodies whether these substances accumulate in our food supply as a result of their use in the production of farm crops or whether they are intentionally added during processing. Because my experience is largely limited to the food-processing phase of the industry, my remarks will refer only to the latter.

Technologists in the food industry are constantly striving to accomplish one or more of the following objectives: (1) lower the cost of production, (2) retard the rate of deterioration from insects, bacteria, enzymes and chemical change, such as oxidation, (3) lower the cost of processing, (4) improve the method of distribution, (5) increase the convenience of prepared foods, (6) improve palatability with respect to odor, flavor, texture, etc., and (7) retain and improve nutritive quality.

Mr. Newton Is Vice President of Swift & Company, in Charge of Research, and Past Chairman of American Chemical Society's Division of Agricultural and Food Chemistry

Chemicals may play an important role in the accomplishment of any of these objectives. It may be said, therefore, that the food technologist has a very considerable interest in the use of chemicals in and on food products.

Now we face a question: How can we accomplish these worthy objectives without creating a hazard for the consumer?

In man's long climb toward civilization he must have exposed himself to almost every kind of organic matter that occurs in nature. He must have learned by bitter experience which natural, growing substances were suitable for food. His experience has not trained his senses, however, to differentiate all the potential hazards of synthetic chemistry or processed foods. I make this point only to be sure that we understand why the consumer is now dependent on the chemical laboratory to aid his senses in telling good food from bad. Chemists and food technologists have created this problem, and they must face it to find a satisfactory solution.

Within the federal government there are several regulatory branches. I would mention two: first, the Meat Inspection Branch of the Agricultural Research Service of the Department of Agriculture and, second, the Food and Drug Administration. How much authority do these branches have with which to safeguard us as unsuspecting consumers?

The Meat Inspection Branch has jurisdiction over all meat and meat-food products shipped interstate, and the law authorizes it to set up regulations governing the interstate shipment of these products, and to provide inspection of such products and of processing plants as may be necessary to see that these regulations are complied with. The regulations have been written to include everything permissible,

and the kind and quality of materials permitted. If a proposed process is not provided for in the regulations, one cannot operate the process in an inspected plant until the regulations are changed. This makes it very simple for the branch to require proof that a new material is wholesome and edible before it will allow use of the material in food under branch inspection. The rigid enforcement of these regulations has given the public confidence that a piece of meat or a meat food bearing the United States inspected-and-passed legend is indeed a wholesome food product.

With the revision of the law some years ago, FDA was authorized to promulgate standards and definitions for food products, and to recognize and set limitations for certain optional ingredients which could not be avoided or which were necessary for processing. Once a standard and definition has been promulgated for a food product, it is unlawful to ship interstate any of this food containing substances not included in the standard. It would seem that adequate authority is provided for full protection from the addition of any untested chemical substance appearing in such food.

More Foods Outside Standards than Within

The Administration has been busy holding hearings and setting such standards, but because of the immensity of the task and the interruption of the war, there are still many more foods outside the standards than within. In the case of unstandardized foods, the law provides authority for FDA to seize any interstate shipment which contains poisonous or deleterious substances. This sounds good, but here is the catch: As the law now stands, FDA must be able to prove that a substance is injurious to the human body before it can prevent the use of that substance in an unstandardized food. This cannot always be done short of a two- or three-year study. Some of the substances are not acutely poisonous, but can be seriously harmful if used over a longer period of time. This circumstance, coupled with the fact that the number of chemicals proposed for use in food has increased greatly in recent years, makes it impossible for the FDA to protect the public on a practical basis under the present law.

A simple change in the law that would require the person proposing the addition of such a new substance to prove its harmlessness would relieve the situation and would provide all the safeguard to public health that is needed. The burden of proof would be shifted

from the FDA to the food processor who proposes to use the new chemical substance.

The reliable food processor with a qualified scientific staff has always taken every precaution to guard against hazard to the public. Such a change in the law would, therefore, require of all processors that which most of them are doing anyway.

Of course, in a case where a chemical manufacturer discovers the utility of a new chemical substance in food and proposes to sell it to the food industry, it should be the manufacturer's responsibility to present such proof to the FDA.

Improvement by Use of Chemical Substances

There is the equally important problem of the many fine physical and nutritional improvements in food which are made possible by the use of a variety of chemical substances which have been proved to be entirely harmless.

Somehow, we must formulate a sound and complete national policy based on a common-sense program for pretesting and reasonable certification of harmlessness of any new substances proposed for use in foods. It is not at all an easy task to lay out the protocols of an adequate testing program for new chemical substances defined as above. I am personally convinced that a satisfactory program for pretesting and certification can be worked out among the chemical industry, the food industry and FDA. Our leading physiologists and pharmacologists are reasonably well agreed that an animal feeding program can be laid out for toxicological and nutritional testing of new chemical substances that will not hinder development or research in finding and utilizing new chemical materials.

Long Usage as Evidence

Where there is well-established usage over a period of time sufficient to cover a man's life span, this usage should be scrutinized as good evidence in the establishment of maximum levels, even though animal experimentation may be incomplete.

For reasons indicated, it would seem to be in the public interest to provide in any revisions of the food and drug law a clear and decisive statement of the requirements necessary to securing approval for the use of such chemical substances. The wording of the law

should be such as first to protect the consuming public, but also to protect the food producer and processor against arbitrary and scientifically unsound rulings of an administrator.

An illustration of such a positive and unequivocal statement of the requirements of the law is to be found in Section 4 of the Meat Inspection Act (21 USCA Section 74), which reads in part as follows:

> . . . and said inspectors shall mark, stamp, tag, or label as "Inspected and Passed" all such products found to be sound, healthful, and wholesome, and which contain no dyes, chemicals, preservatives, or ingredients which render such meat or meat food products unsound, unhealthful, unwholesome, or unfit for human food.

Let us ask ourselves two questions: First, is it a proper governmental function to safeguard the wholesomeness of the American food supply? Second, does the present law provide the necessary authority and mechanism to perform this function?

I shall not present arguments on the first question because I believe every responsible person will say it is a proper governmental function to safeguard the wholesomeness of our food. It is the second question which will raise much difference of opinion.

Propaganda Against Strengthening of Law

There has been a lot of propaganda opposing any strengthening of the food law. The usual points made in this organized opposition run about as follows:

(1) You can't prove a substance harmless because you can't prove a negative. These same people will tell you that they believe these substances should be tested for possible deleterious effects.

That is all anyone expects. Of course you can't prove a negative, but you can get good substantial evidence. The real issue back of this argument is that some people want to be their own referees and decide for themselves when they have made adequate tests. The trouble with such a procedure is that some ill-informed individuals will be in a hurry to get a product on the market, and may allow commercial motives to influence their judgment. There is no emergency facing our food supply which could justify haste at the expense of safety.

(2) Another smoke screen thrown out to confuse this issue is the holding that all substances are chemical in nature, so we don't need any special law to protect us from chemicals. This begs the question. Of course our foods are all composed of chemical substances,

but not all chemical substances are tolerated in our bodies. Some of them are poisonous and have no place in human food. Others are deleterious when in too high a concentration, but wholesome—or even essential—in smaller amounts. Our job is to learn these things *before* we add them to our foods, not *after*.

(3) There has been much objection to a complete testing program on the part of some people on the ground that the costs are too much for a small company to finance. These folks will not come out forthright and say that they want to use the consumer as their test animal because such a procedure is cheaper, but that is what they mean. I'm against it.

(4) There has been much talk against any law that would make FDA the policeman, the prosecuting attorney and the judge, without recourse to appeal. This sounds bad until it is analyzed. Then we find that no one wants to deny the right of appeal, and the argument centers on the kind of appeal to be permitted. From this point on, the argument is a lawyer's argument. That leaves me out. The important point is as to who shall decide whether a proposed new substance has been adequately tested and proven wholesome. Surely, no one will contend that a product of questionable wholesomeness should be marketed pending whatever kind of approval the law requires.

Six-Point Statement of Principles

Now, let us try to state our position in such clear and concise language that no one can possibly misinterpret our views:

(1) We believe it is the responsibility of the food industries to exert every effort toward the production and distribution of foods which are wholesome and nutritious, and to assure adequate safeguards against contamination or adulteration which would render human food unwholesome.

(2) We believe the food industries should continue to improve their food products from the standpoints of nutritive value, wholesomeness, palatability and convenience, but in so doing public health and welfare should continue to be the first consideration.

(3) We believe every substance not represented by long usage in human diet should be subject to question as an ingredient in food, and this question should be resolved by adequate animal experimentation to prove that its use in food does not present a hazard to public health.

(4) We believe every new substance proposed for use in human food should be subjected to adequate pretesting by the manufacturer or user of the substance and that such pretesting should be required by law.

(5) We believe it is a proper function of government to control those factors which may affect adversely public health. Therefore, we believe the results of animal experimentation in pretesting new substances proposed for use in food should be reviewed and approved by FDA before the substance is allowed to be used in food sold to the public.

(6) We believe the Federal Food, Drug, and Cosmetic Act of 1938, as amended to date, does not provide adequate authority for FDA to control the addition of unusual substances to those foods for which standards and definitions have not yet been promulgated, and that the law should be modified properly in this respect.

Endorsement by Trade Association Directors

These principles have been endorsed by the boards of directors of trade associations representing a high percentage of the food industry.

I am told that the O'Hara bill, H. R. 9166, is an effort to put these principles into practice. I have never taken the position either for or against the O'Hara bill because I have had no experience which would qualify me to judge the particular wording. If this bill is so worded that it will put into effect the principles I have just discussed, I think it should be supported. **[The End]**

• FDA REPORT FOR AUGUST •

Fifty-five lots of food unfit for human consumption were seized in August, according to the monthly report of the Food and Drug Administration, released September 23, 1954. A large portion of the 343,568 pounds of food involved was contaminated with filth or was decomposed.

One carload of barley contained a poisonous mercurial compound added as a seed treatment, and a consignment of a soft-drink base was seized because it contained coumarin, a deleterious food flavor. Two other food seizures involved dietary products which were deficient in the vitamins for which claims were made.

The 14 drug preparations seized included eight glandular products. One consisted of therapeutically active hormones, but was only half the strength claimed on the label. The other seven were combinations of inert ingredients that would be worthless for any purpose.

Two dehydrated alfalfa preparations were seized for unwarranted curative claims. Costa Rican Maya leaves were also seized because the importer misbranded them with false claims of efficacy.

By FREDUS N. PETERS

The O'Hara Bill

Its Effect

THERE APPEARS to be a wide divergence of opinion regarding proposed chemical-additive amendments to the Federal Food, Drug, and Cosmetic Act of 1938. Does this arise through misunderstandings of the facts or because of differing basic philosophies? If there is a misunderstanding of the facts, a program such as this should clarify matters. If different fundamental concepts are involved, the sooner that fact is understood, the better.

The comments in this paper are predicated upon a belief that the following statements are true:

(1) The intentional use of food additives, both synthetic and natural, has improved foods in many ways, and it is in the public interest that this practice be continued and encouraged. Like any other tool used by industry, additives should be applied correctly so the user will be benefited, not harmed.

(2) The rate of progress in any industry depends upon the ingenuity and efficiency of application of new tools, whether these be processes, products or methods. Scientific research is the systematic and orderly development of these new tools. In other words, I believe that the rate of progress in an industry depends upon the rate at which improvements developed by research are applied.

(3) The incentive to research can be maintained only in an atmosphere of freedom to apply the fruits of research, and this freedom carries with it responsibility for results of that application. Freedom and responsibility must be coexistent. Neither can long exist alone.

(H. R. 9166)—
on Food Research

The Author, a Vice President of The Quaker Oats Company, Chicago, Notes Portions of the Bill Which He Believes Are Objectionable. He Addressed the Recent Meeting of the ABA Division of Food, Drug and Cosmetic Law

(4) It is the responsibility of the food industry to provide clean, wholesome, honestly labeled foods, and the best foods which modern science, engineering and production can furnish.

(5) It is the responsibility of government to establish rules and regulations safeguarding the public's right to receive an ever-increasing variety of wholesome new food products. Promulgation of a template for daily living or prescription of the components of the national dietary is not a government function.

(6) In discussing H. R. 9166, entitled "A Bill to Protect the Public Health," a layman must assume that each phrase and clause was inserted for some specific reason and that the powers granted the Secretary of the Department of Health, Education, and Welfare would be exercised, should the legislation be enacted into law.

You, being experts in this field, may disagree with this last point. At least, a prominent government employee told me that no food and drug official would attempt to enforce all the provisions of this bill because it would be suicidal to do so. He further said that there were risks inherent in any legislation, and the food industry should have faith that the Secretary would exercise restraint in applying the provisions of such a bill. However, I believe history shows that some governmental agencies not only have exercised all the powers granted

directly by an act, but by administrative regulations have extended their powers beyond the original intent of the law. In this situation, one is justified in making the assumption just suggested. Be that as it may, I shall refer to portions of H. R. 9166 which I believe are objectionable.

Proposed Definition of "Chemical Additive"

Proposed Section 201(s) defines a new chemical additive as:

> . . . any substance the intended use of which results or is likely to result in its becoming a component of any food, including substances intended to preserve or alter the food *or for any other* purpose in manufacturing, producing, processing, packing, wrapping, transporting, or holding the food, which is not generally recognized, among experts . . . as having been adequately shown through scientific procedures or through prolonged use in food not to be a poisonous or deleterious substance for its intended use. [Italics supplied.]

Prior bills have defined a new chemical additive in much simpler terms, such as: "Any substance designed to alter a food in any way." The present bill goes beyond intentional additives and apparently includes under the category of "new chemical additives" any substance which can find its way into food because it is present where the food is manufactured, stored, packed or shipped. Such substances conceivably could include sprays, paints, sweeping compounds, detergents or any other product housed in the processing plant or warehouse. However, under the present law, food contaminated by any such products would be adulterated. Therefore, a layman must assume the definition is designed to cover something additional. In view of later sections of this bill, is it intended that the processor must file an application for permission to use any new paint, lubricant, refrigerant or window cleaner in a food plant?

Vagueness a Hazard to Processors

The phrase "not generally recognized, among experts" is so vague that a processor could not plan any research program involving a new product with any confidence. Does the phrase mean there must be unanimity of expert opinion? Let me emphasize here that in chronic-toxicity studies there is seldom a clear-cut objective test. Since a decision regarding chronic toxicity is so frequently a subjective matter, you of the legal profession will be the first to recognize the practical impossibility of obtaining agreement among experts. Does the phrase mean a majority and, if so, a majority of what?

Without belaboring the point, I would say that it seems to me that a processor confronted with this question must go to the Secretary and ask whether the product may be used. Expressed in another way, the conservative processor will not use his own judgment or that of his scientific experts, but will relinquish to the Secretary his freedom to exercise judgment as to his own products.

The phrase "through prolonged use in food" is likewise vague. Does it mean six months, six years or 60 years? Does it mean years of use in a single food of limited distribution or months of use in many foods? To settle this question, the processor again goes to the Secretary for a decision.

This section requires that the product be not deleterious or poisonous for its intended use, but there is retained the already-existing prohibition against the use of any poisonous or deleterious substance. Section 402(a)(2), as amended, says that a food is adulterated "if it bears or contains any added poisonous or added deleterious substance."

More Questions Calling for Clarification

There can be a great difference between the toxicity of a chemical consumed in unlimited amounts and a public health hazard created by the use of that chemical in minute amounts in a food. Which sections of the law will be applicable? Suppose a manufacturer goes to great expense attempting to show that an additive is harmless at a level of 0.2 per cent but admits it could be deleterious at a level of 2 per cent. Has he convicted himself of wishing to violate Section 402(a)(2)?

Thus, Section 201(s) is so broad and so vague that a conscientious manufacturer has no firm base upon which to build a research program.

Before investing substantial sums in certain projects, the manufacturer will need answers to such questions as:

(1) Has this additive been proven safe through prior use?

(2) Is there sufficient toxicological data already available to warrant use of the additive in food?

(3) Is this additive likely to be considered new?

(4) Is there any basis, however flimsy, for competitors to successfully attack the safety of the additive?

All responsible food processors ask the first two questions in one form or another, and the scope of the research program depends upon the answers. At the present time, questions 3 and 4 need not be asked but, under H. R. 9166, they become important. Even more important,

the Secretary is the only one who can give the answers to these questions. The freedom of the manufacturer to exercise judgment on any of these points is destroyed.

Proposed Section 409(b)(A) requires that an application for use of a new chemical additive shall contain its name, chemical identity and composition. Chemical identity and composition, to a chemist, mean the quantitative amounts of specific substances of known molecular structure. Such information is not available for most naturally occurring substances. I can't even give the chemical identity and composition of oatmeal. Why include such a requirement in the bill?

Requirement in Section 409(b)(C)

Section 409(b)(C) requires that the application shall contain "a full description of the methods used in . . . the production of the new chemical additive . . . ." This has nothing to do with public health or pure foods. A small manufacturer may have relatively inadequate facilities and his methods may be crude, but he may have a secret process or an unusual combination of old processes. However, if his food is wholesome, it is none of the Secretary's business to know how he achieved his results.

Section 409(b)(D) requires that the application contain "a description of the methods for quantitative determination of the new chemical additive, and its reduction products, in or on food." It is impossible to determine with any reasonable degree of accuracy the amounts of many natural substances when they are included in a food. It is a practical impossibility to determine accurately the amount of soya bean in a mixture of ground meat, cereal and soya. Then there is the phrase "and its reduction products, in . . . food." This phrase is extremely ambiguous. Fats react with many flavoring materials; sugars react with protein. Are these reduction products? No one knows just what reactions occur even in such a commonplace procedure as the baking of bread. Possibly the Secretary would not require analytical methods for such products, but could the absence of such methods be construed as a basis for rejection of the application?

Within 120 days after filing an application, the Secretary must either issue a regulation announcing that the new chemical additive is not a poisonous or deleterious substance for its intended use or he must notify the applicant that no such regulation will be issued. With the announcement of safety, the Secretary assumes responsibility

for the complete safety of each and every product, including reduction products (whatever they are), that will be used in foods and he must assume or reject that responsibility within four months. The responsibility for safety is shifted from the manufacturer, where it has always been, to the Secretary. What would you do if you were the Secretary? How rapidly and how many new products would be approved if you were the Secretary?

Food research is extremely expensive. As president of a food company, how much research money would you invest, knowing that eventual application of that research would lie in the hands of a single man who would have to assume responsibility not only for the safety of your products, but for those of thousands of other companies as well? One needs no crystal ball to see what this provision will do to food research.

Burden on Secretary of Health, Education, and Welfare

H. R. 9166 provides for the appointment of a scientific advisory committee upon request by either the applicant or the Secretary. The Secretary would appoint the committee, presumably from a list of names to be furnished by the National Academy of Sciences. The size of the committee would be determined by the Secretary and if the National Academy of Sciences did not furnish a list, the Secretary could appoint a committee completely of his own choosing. The committee would have a maximum of 90 days in which to make a recommendation. There are objections to this procedure. I shall mention but one:

The Secretary still must assume sole responsibility for safety. Obviously, he could not be a disinterested party, and it is equally obvious that he could appoint a committee that would almost assuredly bring in any type of decision he desired. Give me the power to name the personnel and size of a committee, and I can get any kind of a decision I desire. It must be remembered that we are dealing with something that usually cannot be proved objectively. I could pick committees of recognized scientists who disapprove of the entire cereal-enrichment program or the widespread use of ready-to-eat cereals or the use of the amount of sugar and salt we have in our national dietary. I also could appoint committees of equally prominent men who would approve of these things, and so could you. Therefore, the scientific advisory committee as provided for in this bill is merely

another tool through which the Secretary can impose his will upon the food industry in such degree as he may desire.

Proponents of this bill have characterized the Secretary as a disinterested, impartial umpire, thus implying that the manufacturer's interests are opposed to the public interest. This implication is just as false as is the assumption that the Secretary can be a disinterested party. If he approves the use of some product which later proves to be less than harmless, his career may be wrecked. It will be far safer for the Secretary to assume a negative position than to maintain an open mind. This is no reflection upon the Secretary; it is merely a recognition of normal human reactions. Again I ask: What would you do if you were he?

What Bounds for Scientific Advisory Committee?

In view of Section 409(b)(B), to be discussed in a moment, is there any assurance that the scientific advisory committee will be asked to limit its consideration to matters of toxicity and protection of public health? Would the committee be free to consider questions of functional value and use? A group of eminent toxicologists, physiologists or public-health experts may have less competency in this field than some men who never look inside a scientific textbook. The best pharmacologists in the world may be ignorant on questions involving the degree of product improvement imparted by a chemical additive.

If there should be legislation providing for appointment of a scientific advisory committee, why should it not include some scientists appointed by the applicant? Even though one may believe that the manufacturer should be denied the responsibility for approving his products, why should he be denied any representation upon a committee which considers his products?

"Functional Use Information"

Proposed Section 409(b)(B) requires that the application show "the proposed use of the new chemical additive together with functional use information." Section 409(c) states:

> The Secretary shall, in determining whether the proposed ingredient is a poisonous or deleterious substance for its intended use, consider among other relevant factors—
>
> (1) The functional value of the proposed additive for its intended use . . . .

Since when has the degree of toxicity or harmfulness of any substance been modified by reason of its functional use? An additive is poisonous or is not poisonous regardless of whether it functions as a sweetener, an emulsifier, an astringent, a preservative or an antioxidant. I heard arguments in Washington in 1945 against relaxing curbs on sugar because it was said the American public eats too much sugar and imposition of curbs was the best way we ever had to reduce the amount of sugar in the dietary. I believe any move to give the Secretary power which can be exercised on the basis of his conception of functionality of any food is dangerous and contrary to public interest.

The Secretary has already ruled out certain products, partly because they allegedly made bread appear fresher than it was. Presumably, if someone found an additive that would make a six-month-old corn flake taste like it had just come from the oven, the Secretary could reject it merely because he did not approve of its function or because the public might be confused as to the age of the cereal.

Is that concept to be applied to the cosmetic industry so no woman will be permitted to appear younger than she is? As far as I am concerned, such deception in women and in foods is highly desirable.

Parenthetically, this section appears to contravene the very title, which is "A Bill to Protect the Public Health." What connection does the functional value of a food have with protection of public health?

Answers Necessary Before Managements Begin Projects

Before approving a research project, most managements will require rather specific answers to many questions, of which but three are mentioned:

(1) How much time will be involved?

(2) Is the objective desirable from both company and public standpoints?

(3) What is the estimated cost?

If H. R. 9166 is enacted into law, no satisfactory answers to these questions can be given with regard to research on any new food or food product.

The length of time depends entirely on how much evidence the Secretary demands in the application. Complete harmlessness under any and all conditions can never be established. Hence, the amount of evidence to be assembled rests entirely with the Secretary. He could very easily ask for data which would require years to assemble. Therefore, Question No. 1 cannot be answered.

With regard to Question No. 2, H. R. 9166 introduces a totally new concept. The desirability of the research objective must now be approved by the Secretary because if the objective is a product or process designed to change the color, odor, taste, texture, nutritional value or stability of a food, the use of a chemical additive is almost certain to be involved. It would be a bold manufacturer who would finance research on any new product without obtaining tacit approval from the Secretary, and it is difficult to believe the Secretary would give any kind of approval till all the facts were available.

Therefore, since the time of research cannot be estimated and the desirability of the objective cannot be assessed, it is impossible to estimate the cost of the project. With these three basic questions unanswered, research directors will have extreme difficulty in obtaining authorization to inaugurate any really important studies.

Morale Factor

Aside from financial support, the productivity of any research organization depends upon its morale. With the responsibility for safety transferred to the Secretary and with his power to reject a development because he disapproves its fundamental objective, there is little freedom and even less responsibility left to the research man. Without these, there is no incentive, and morale is lost.

These reasons make it very unwise, in my opinion, to give favorable consideration to many of the provisions of H. R. 9166. **[The End]**

• SECRETARY HOBBY APPOINTS HARVEY, ROE •

Appointment of John L. Harvey as Deputy Commissioner of the Food and Drug Administration under Commissioner George P. Larrick was announced on October 7 by Oveta Culp Hobby, Secretary of Health, Education, and Welfare. Simultaneously, Mrs. Hobby announced that Robert S. Roe, formerly FDA's director of program research, is appointed to succeed Mr. Harvey as an Associate Commissioner.

Mr. Harvey and Mr. Roe are career members in civil service. Both of them joined the Bureau of Chemistry in 1925.

Food Law Amendments from the Scientific Viewpoint

By PAUL LOGUE

Presented at the August 17 Meeting of the Division of Food, Drug and Cosmetic Law of the American Bar Association, at Chicago, This Discussion Emphasized Major Reasons for Incorporating New Substances Other Than Agricultural Products into the Food Supply, and the Need for FDA-Industry Cooperation

IT IS A GREAT PLEASURE for me to have the privilege of speaking before this group today. Not being a lawyer myself, I will not attempt to discuss from a legal standpoint the detailed provisions of the various possible amendments in existing food law that have been introduced by members of Congress in the recent past. Instead, in accordance with the invitation which I received from Mr. Charles Wesley Dunn, I will direct my remarks to the scientific viewpoint as it is related to our food supply.

In considering the subject that is before this group for discussion today, I take as my starting point the belief that each of us is expected to express his personal views. Accordingly, while I am chairman of the Chemicals in Foods Committee of the Manufacturing Chemists' Association, the views that I wish to express here are my own.

At the outset, I think that there is one viewpoint that I cannot emphasize too often or too strongly—namely, my belief that it is undoubtedly the common objective of the food industry, the chemical industry and the government that the food and drug law be modern and realistic, and that there be an adequate pretesting with respect to safety of any new substance that is to be incorporated in our food supply.

To those accustomed to thinking of food as natural substances, the question may quickly arise: "Why add anything to our food? Isn't

Mr. Logue Manages Market Development, Monsanto Chemical Company, St. Louis

it good enough just as it is?" It may come as a surprise to such people that in truth very few of the foods that reach our table are "raw agricultural commodities." One can think of only a few—such as fruits, lettuce, tomatoes, eggs—among our typical foods that may be classed as "unprocessed raw agricultural products." By far the major portion of our food supply comes under the classification "processed foods" and may, therefore, be subject to treatment with substances not naturally present.

Before a group such as this, however, the necessity for incorporating various processing agents and additives to improve our food supply is undoubtedly too well known and too widely accepted to require extensive discussion. Just summarizing briefly, I would say that there are four major reasons for incorporating substances other than agricultural products themselves into the food supply, and I think these four major reasons can be summed up as follows: (1) to produce desirable changes in the food product, (2) to prevent undesirable changes in the food product, (3) to prevent spoilage of the food product and (4) to compensate for deficiencies which may exist in the food product in its natural state. I should like to discuss each reason.

Producing Desirable Changes in Food Product

In food processing, products often are added to produce desirable changes in color, flavor or texture. Such has been the long-time use of caustic soda in the manufacture of "Dutch process" cocoa. Such also has been the use of nitrous oxide, nitrosyl chloride, benzoyl peroxide and chlorine dioxide in flour. None of these substances, which have been in use for years, constitutes a hazard to the public

health under the conditions of use. So, too, may be considered the use of ethylene in coloring celery and oranges, hydrogen peroxide in improving the texture of cake batters, nitrous oxide in pressurizing whipping cream, and sodium methoxide to improve the plasticity of lard. Calcium chloride increases the firmness of tomatoes, sodium polyphosphates the firmness of pectinate gels, and enzymes the tenderness of peas.

The beneficial effects to be derived from the use of monosodium glutamate to enhance the flavors of soups and sauces; of gelatin, gums and glyceryl monostearate to control the physical characteristics of ice cream; of enzyme solutions to tenderize beef carcasses; and of sodium citrate and phosphate to homogenize cheese are so well recognized as to be generally accepted without question.

Preventing Undesirable Changes in Food Product

Foods in general are subject to degradation from a number of influences, including bacterial, fungal and enzymatic attack; oxidative changes; and changes in physical state. Refrigeration retards some undesirable changes, but in many cases resort to the use of chemical additives has proved to be a real boon to the food industry.

Examples are the use of salt and spices in preserving meats; the use of propionates to inhibit mold growth in bread; the use of propylgallate, nordihydroguaiaretic acid and butyl hydroxyanisole in preventing rancidity in animal and vegetable fats; and the use of glyceryl monostearate to retard the staling of bread.

Preventing Spoilage of Food Product

Chemicals used to prevent spoilage of food products range from well-established favorites, such as sulfur dioxide and sodium benzoate, to the more recent sorbic acid and antibiotics. They play a vital part in an important segment of our food supply.

Compensating for Deficiencies Which May Exist in Food Product in its Natural State

As the science of nutrition has advanced, we have come to realize that none of our foods is complete in itself, and deficiencies have become evident. Even the commonly recognized most perfect food, milk, is deficient in iron, copper and cobalt. One of the most spectacular achievements in animal husbandry has been the increase in viability of little pigs by inclusion of these chemical elements in the early diet.

It has been shown to be desirable to enhance the nutritional quality of many of our basic foods by supplementary additions of substances in which the foods are nutritionally deficient, for example, (1) *bread* enriched with thiamine, riboflavin, nicotinamide, calcium and iron, (2) *milk* homogenized and enriched with vitamin D, (3) *margarine* enriched with vitamins A and D and (4) *jellies and fruit butters* with added pectin and acidulants to compensate for fruit deficiencies.

As we come more and more to the concept that the standard should not be what nature put into the food but what man's nutritional requirements are for maximum development in his present environment, we may anticipate that other foods will be fortified with other nutritional substances found desirable in the light of advancing knowledge.

The foregoing is intended to show that the use of chemicals in foods is not new; their use is not capricious; they serve a definite and beneficial purpose; they will continue to be used; and, as new needs arise and are recognized, new chemicals will be found to serve them. One might easily accept the hypothesis that every chemical element, however minutely present, may have some function in our nutrition.

All that I have been discussing are, I feel, matters that are in the realm of our common objectives, and I take it that no one would seriously suggest that anything be done, by legislation or otherwise, that would prevent the accomplishment of these desirable aims.

The question, of course, is how to continue to accomplish these objectives and how, at the same time, to make sure that any new substances incorporated in foods, whether such substances are natural substances or the products of chemical reaction, are adequately pretested with respect to safety.

In this connection, I myself was greatly impressed by the address which Mr. Dunn gave in Los Angeles on June 29 of this year, when he spoke before the Institute of Food Technology. I was particularly in agreement with Mr. Dunn's statement to the effect that the food industry and the chemical industry face a common problem here which should be met by cooperative action of the two industries.

In Mr. Dunn's June 29 remarks, he discussed the new O'Hara bill in some detail. These details are more properly dealt with by lawyers than by scientists, and I will therefore confine myself to the observation that the new O'Hara bill undoubtedly contains both good points

and bad points, and this, I understand, is one of the major matters to be discussed at this meeting in Chicago. One aspect of the new O'Hara bill that seems to me to represent a significant step forward is the recognition in the bill of the fact that the safety of any given substance must be considered in the light of "its intended use." This is in agreement with what has long been my view, since, from the scientific standpoint, it is clear that any substance can be regarded as harmful if it is viewed abstractly and without regard to the quantities, frequency or manner in which the substance is expected to be consumed.

With respect to any new legislation that may be enacted, public benefit should, of course, be the prime objective. New substances proposed for introduction into foods should, therefore, be subject to adequate pretesting with respect to safety under the conditions of use. I believe it is generally agreed that such information—together with pertinent physical, chemical, and analytical data and methods—should be furnished the Food and Drug Administration before introduction of the substances into foods is undertaken.

It is my belief that if such information is supplied to the Food and Drug Administration, it should be possible to market the substance in a specified time unless the Food and Drug Administration objects on specific grounds. If the Food and Drug Administration does object, there should be informal private conferences to resolve differences—and provision should also be made for *ad hoc* advisory committees of scientific personnel, available to either party. If, after these various procedures, differences between the parties cannot be resolved, I believe that the Food and Drug Administration should have the right to seek an injunction on the issue that there is inadequate evidence of safety or on the issue that the substance proposed to be added is affirmatively harmful.

No one expects the Food and Drug Administration to resort to intensive research for the purpose of finding out what new substances should be added to food to make it more nutritious or to enhance its value in color, appearance, flavor or form. This, rather, is the function of the food industries and their suppliers, and no legal barriers should be erected that would diminish the incentive constantly to improve our food supply in this fashion.

I look forward to the opportunities which this meeting will afford for further discussion of these important matters. **[The End]**

Intentional-Food-Additives Legislation

IT HAS BEEN MY PRIVILEGE for several years to work closely with various members of the chemical industry on the problem of new legislation affecting intentional food additives. That work has brought me into touch with members of the food industry who are equally interested in the subject.

It is my impression that a majority of food-additive producers, sometimes referred to as "the chemical industry," feel that changes should be made in existing laws affecting the use of new additives. The reason for this feeling is not surprising. The portion of the "chemical industry" concerned with the food-additive question is in reality a part of the food industry itself. For the most part, it is fully sensitive to the delicate character of food production and to the high degree of public responsibility that goes with it. This is true, if for no other reason, because of its close contact with food customers. The food-additives industry knows the immediate and ultimate values of putting safety first and of seeing to it that our laws are fully strong enough to protect the public health.

It has been asked recently why makers of food additives have not taken a firmer position for or against specific legislation. The answer is that they have wanted to work with the rest of the food industry in arriving at a solution. Production of foods in which additives are contained is generally a joint project between suppliers and buyers of the additives. Safety and wholesomeness of food are determined not only by the character of the ingredients but by the quantity and manner in which they are used. Any new law that goes to the heart of safety must take into account both of these factors. It is for this reason that the majority of those who produce additives have come to consider it essential that the two parts of the industry

By FRED BARTENSTEIN, JR.

The Author, Counsel for Merck & Company, Inc., of Rahway, New Jersey, Expands His Remarks Before ABA's Food, Drug and Cosmetic Law Division at Its August Meeting

try to arrive at a joint solution. Efforts for several years have been directed toward attaining that solution.

Actually, a great deal of progress has been made in bringing various viewpoints together. It appears that food-additive makers agree with most of the basic principles publicly asserted by some of the food groups. They agree with the premise that every new ingredient proposed for use in food should be adequately pretested for safety before use. They agree with the principle that no man should be his own referee on the issues of safety and adequacy of safety testing. But they urge that he continue to bear full responsibility for his own compliance with law and that the refereeing be by traditional policing and court actions. There seems to be general agreement that all testing data on a substance should be supplied to the government ahead of its use in foods.

Some of the food people have proposed that the Food and Drug Administration should finally be permitted to say "yes" or "no" to the use of an ingredient before it is put to use, based on its views of adequacy of testing and its views of relative safety in the light of usefulness. Other food people feel that FDA has adequate powers under existing law. Still others have pointed out that existing law has a disadvantage in being interpretable to forbid an additive that has a safe use.

There is a middle-of-the-road approach shared, I believe, by the majority of food-additive producers and by a substantial number of food-industry representatives. This approach is prompted by the

belief that the Federal Food, Drug, and Cosmetic Act is and should remain basically a policing measure. Practically all the mandates of the Act—and most of them involve similar issues of public health and safety—are enforced as policing measures. The industry is given the rules and is expected to abide by them. Failure to obey the rules results in policing action by FDA. Before further extension of the licensing type of control—such as that on food colors, new drugs, insulin and antibiotics—a bona-fide effort should be made to strengthen existing rules, remove defects and furnish new enforcement weapons. The following rather specific additions to the federal food and drug Act comprise that middle-of-the-road approach, given a great deal of thought by industry representatives. If these changes were adopted, they would result in a significant strengthening of the statute:

(1) Add a new provision to the Federal Food, Drug, and Cosmetic Act that no new ingredient intended for food use should be shipped in interstate commerce or used in foods unless the shipper or user submits to FDA his full data on safety.

(2) Add a provision that the Administration have a reasonable time in which to review this data.

(3) Amend the law to provide that it is a violation to ship an ingredient (or a food containing it) which is unsafe in the manner used or intended to be used, or which has been inadequately tested for safety for food use.

(4) To resolve initial differences between FDA and the supplier or user of the ingredient, add a provision for informal conferences and, possibly, for advisory scientific bodies to be available to either government or industry.

Additions to Act Would Prevent Use of Unsafe Ingredients

The resulting law would not allow an untested or unsafe ingredient to be used before FDA discovers its existence or while the Administration tries to get evidence to prove it is unsafe. Prior notice and time for evaluation of submitted data is a prerequisite to shipment or use. If the Food and Drug Administration is of the opinion that the ingredient should not be used, it can move, before such ingredient reaches the market, by the traditional procedure of injunction. If that agency is right in its position, what it needs to succeed in the courts is immediately at hand: evidence showing lack of safety or showing inadequacy of testing.

The proposed changes would leave the supplier free to ship the ingredient or the user to use it at the end of the prescribed periods, whether or not there has been final agreement with FDA unless, of course, the Administration takes the matter to court, as noted above. This procedure has the advantage of not giving to FDA the power of vetoing the ingredient and, therefore, of not having to shoulder any of the supplier's or user's primary responsibility.

I believe that in the great majority of cases, as now, agreement would be reached between the supplier or user and the government. In cases where there would be disagreement, the courts would decide the issues in the first instance, with the enforcing agency bearing the burden of showing lack of safety or inadequacy of testing, not an unfair burden with all the evidence that would be necessary for the determination at hand.

Operating Power Could Be as Great as Legal Power

The Administration's practical operating power under such an amended statute would be perhaps as great as its legal one. There would be few instances in which a supplier would be bold enough to go ahead with sales of a proposed ingredient if FDA were dissatisfied with the submitted evidence. Of interest to food companies, anyone wanting to may determine from the Administration directly whether a notification has been filed on any proposed ingredient and whether the official attitude is favorable or unfavorable.

This increase of FDA police powers seems to me to be justified in the interest of public-health protection. It would better accord with scientific realities than the present law. It has the virtue of protecting the industries against arbitrary, timid or nonscientific decision, and it does avoid further travel down the trail of government licensing control over the food, drug and cosmetic industries. This, of course, is a policing measure, and requires active enforcement. It is axiomatic that the Administration should have the people and the facilities and, therefore, the funds to enforce it thoroughly.

These changes which, as I have said, have the close attention of representatives of the food industry, particularly of the food-additive producers, may yet be the genesis of an industry-wide bill. **[The End]**

By JOSEPH M. CREED

COMMENTS ON THE H. R.

H. R. 9166, popularly referred to as the O'Hara bill, is an attempt to meet an increasingly impressive problem resulting from the tremendous stimulus given to the development of new chemicals and new uses for old chemicals during and since World War II. The problem was brought into sharp focus during the bread-standards hearings before the Food and Drug Administration. The long-drawn out controversy in those 1949 hearings over the possible toxicity of chemical emulsifiers which had been introduced into the baking industry during the fats-and-oils shortage of World War II diverted attention from the main objective of the hearings to such an extent that the baking industry found itself in the hapless role of little more than an interested spectator.

It became obvious to participating industries as well as to the Food and Drug Administration that unless some procedure was established to eliminate discussions of questions of toxicity from standards-of-identity hearings and to confine such hearings to the statutory objectives, the standard-making process would be slowed down considerably and the cost of participation become almost prohibitive.

The problem was not, of course, confined to foods for which standards were to be established. It transcended that limited area to all foods to which, at some time or other, there might be added new chemical components.

O'HARA BILL—
9166

The Author, Counsel for the American Bakers Association, Participated in the Panel Discussion on the Question of the Regulation of New Chemical Additives in Foods Held by the Division of Food, Drug and Cosmetic Law in the Section of Corporation, Banking and Business Law of the American Bar Association at Chicago August 17

The Congress of the United States first took cognizance of the problem through the establishment of the Gillette Committee, which conducted hearings in 1949, and the enactment of the Keefe resolution, introduced by the late Congressman Keefe of Wisconsin in the House of Representatives during the Eightieth Congress. From the Keefe resolution, there subsequently evolved the Delaney Committee to investigate the use of chemicals in foods, which explored extensively, if somewhat one-sidedly, the entire problem of how the new chemicals and pesticides should be handled. Out of these hearings came several bills introduced by Representative Delaney of New York and Representative Miller of Nebraska,[1] a member of the Delaney Committee.

Originally, these bills combined the control of pesticides and chemical additives in one proposed amendment to the Food, Drug, and Cosmetic Act. Chemicals were subsequently split off, and the pesti-

[1] H. R. 2245, by Congressman Delaney; H. R. 4901 and H. R. 4277, by Congressman Miller.

cides problem was handled through H. R. 7125, which eventually passed both Houses of Congress, after extensive revision, and was enacted into law [2] in July of this year.

Meanwhile, the problem of chemical additives in food was marking time, partly because the problem of pesticides fully occupied the Congressional legislative committee and partly because of the divergence of viewpoints among food and chemical groups interested in the problem. As the pesticides bill gradually cleared the various hurdles and a pattern of what Congress would accept in the way of amendatory legislation became clear, H. R. 8418, the original O'Hara bill, was introduced by Representative Joseph P. O'Hara of Minnesota, second ranking Republican member of the House Interstate and Foreign Commerce Committee.

This bill was subsequently amended after conferences, and H. R. 9166, a substitute bill, was introduced by Mr. O'Hara. The essence of the bill may be summed up in two major concepts of this complex problem. It requires: (1) adequate pretesting of new chemicals, before use in food, to establish their harmlessness when consumed by humans and (2) approval by the Food and Drug Administration in advance of its use in food that a new chemical additive is, in fact, harmless for its intended use.

The bill in its embodiment of these two major concepts reflects the views of several major food industries—such as the baking, milling, dairy, meats, and fats and oils industries, among others—as set forth in statements of principles, adopted by these groups, which are substantially similar in content, although with minor variations in text.

One of the first problems faced by the drafting group was the development of a satisfactory definition of "new chemical additive." It was a stumbling block which required much agility to scale. The grandfather-clause technique was considered, but was discarded as undesirable because of the difficulty in setting a precise cutoff date. The alternative was to find a common denominator which could be the basis for a relatively precise and accurate description of a new chemical additive. It was concluded a chemical additive, to be "new," should be one not generally recognized by qualified experts as being a nonpoisonous or nondeleterious substance for its intended use either on the basis of (a) scientific testing procedures or (b) prolonged use in food.

[2] Pub. L. 518, 83d Cong., approved July 22, 1954.

Having set up the two marks of identification for a new chemical additive in the definition, it seemed desirable to include within the scope of its coverage any possible effect which the intended use might have on food wherein it might be used. From this reasoning, there resulted the following definition:

> (s) The term "new chemical additive" means any substance the intended use of which results or is likely to result in its becoming a component of any food, including substances intended to preserve or alter the food or for any other purpose in manufacturing, producing, processing, packing, wrapping, transporting, or holding the food, which is not generally recognized, among experts qualified by scientific training and experience to evaluate the toxicity or other potentiality for harm of such substances, as having been adequately shown through scientific procedures or through prolonged use in food not to be a poisonous or deleterious substance for its intended use. The term does not include pesticide chemicals in or on raw agricultural commodities.

Thus, the bill now embraces the two major concepts or elements of the food industries plus a definition which spells out the extent, as well as the limitations, of the proposed coverage.

Proposed Application Procedure

The bill would amend the Food, Drug, and Cosmetic Act through the addition of a new Section 409 in Title IV, whereby a procedure is established by which a new chemical additive might be proposed for use in food. Under the amendment, any new chemical additive falling within the definition would be excluded from food unless the Secretary of Health, Education, and Welfare by regulation declared such additive to be safe for its intended use. The proposed procedure would give *any* interested party the right to file with the Secretary an application to permit incorporation of a new chemical additive in food. The applicant would have the obligation of furnishing the Secretary certain information to support the request.

The application would spell out the additive's identity, its composition and proposed use, a description of the methods used in its production, and a quantitative determination of it and its reduction products in or on food. Directions for its use and proposed labeling and full reports of investigations with respect to toxicity or other potentiality for harm, as well as a proposed regulation for the use of the additive, would be included in the application.

Following submission of the application, the Secretary of Health, Education, and Welfare would have a maximum of 120 days to act on

the proposal. Within that period of time the applicant can require, or the Secretary may cause, referral of the matter to an advisory committee composed of experts qualified on the subject matter of the application and of adequately diversified background. They would be selected by the National Academy of Sciences or, in the event of failure of the academy to make the selection, the Secretary would be empowered to do so. If the proposal is referred to such a committee, its findings must be reported back to the Secretary in a maximum of 90 days.

Publication of Regulation and Filing of Objections

In not later than 30 days from receipt of the recommendations of the scientific advisory committee, the Secretary would be required to make public a regulation announcing whether the available scientific data establish that the new chemical additive is or is not a poisonous or deleterious substance for its intended use. It would be obligatory for him to state the reasons for his action. This regulation will be effective upon publication. Within 30 days after publication, any person adversely affected could file objections with the Secretary whereupon, after due notice, a public hearing will be held for the purpose of receiving evidence relevant and material to the issue raised by such objections.

The bill provides in Section 409(e) that all the material from the advisory committee shall be made a part of the record of the hearing if relevant and material, subject to Section 7(c) of the Administrative Procedure Act.

A member of the advisory committee—at the request of the Secretary or applicant, or the officer conducting the hearing—would be called upon to testify with respect to the report and recommendations of the committee.

As soon as practicable after completion of the hearing, the Secretary shall act upon such objections and make public a regulation. Following the usual pattern, this regulation would be based only on substantial and probative evidence adduced at the hearing, including the report, recommendations, underlying data and reasons certified to the Secretary by the advisory committee. The order may not take effect prior to the ninetieth day after its publication. Thus, in case of proposals involving no public hearing, we have a maximum of 240 days before the regulation will be issued. Should a public hearing be called, that time would necessarily be extended to a period "as

soon as practicable after completion of the hearing." Additionally, there would be 90 days after publication before the regulation would become effective. Provision is made for the applicant to consult with the advisory committee in connection with his proposal. Similarly, provision is made for judicial review by direct appeal to the United States Court of Appeals within 60 days after the entry of an order by the Secretary. This provision follows generally the procedure required under the pesticides bill and Section 701(f) of the Federal Food, Drug, and Cosmetic Act.

The bill sets forth four criteria which, it is intended, the Secretary shall consider, among other relevant factors, in formulating a judgment as to whether or not the proposed ingredient is a poisonous or deleterious substance for its intended use. These are: (1) the functional value of the proposed additive for its intended use, (2) the probable consumption of the new chemical additive and any food in which it is intended to be used as a component, (3) the cumulative effect in the diet of the same or any chemically or pharmacologically related substance or substances and (4) appropriate safety factors for transposing animal experimentation data to practical use in appraising the hazard to man.

Factors to Which Secretary Must Give Consideration

It should be emphasized that these four criteria are not conclusively binding on the Secretary in making his determination either for or against the proposed order. They do, however, give emphasis to certain factors to which consideration must be given by him even though they are not necessarily the final determinants. The first factor, we think, properly requires that consideration be given to the value to the consumer of a proposed new additive, on the theory that the Act itself is basically designed for the protection of the consumer. It is proper for the Secretary to inquire as to the benefits which the consumer will derive from the use of a new additive. On the other hand, it is not intended by the "functional" criterion to authorize the Secretary to deny an application simply on the basis that there is disagreement as to the degree of usefulness between the Secretary and the applicant. If, however, the Secretary finds that the substance is in fact worthless for the claimed purpose, this fact might be taken into account in the Secretary's determination.

The second factor is perhaps in the field of conjecture, since the "probable consumption" of the new additive in any food in which it is intended to be used cannot be determined with certainty. Nevertheless, there is sound reason for requiring the Secretary to consider such probable consumption in order that a reasonable appraisal may be made of any actual or potential synergistic effect.

The third factor, by requiring the Secretary to consider the cumulative effect of ingestion of the proposed additives, recognizes the existence of possible disadvantages to the consumer, from a pharmacological standpoint, which could be potentially so dangerous as to counterbalance other advantages which the proposed additive might have.

The fourth factor spells out what unquestionably is considered good scientific procedure in analyzing a new ingredient to be consumed by humans, namely, to give due consideration to appropriate safety factors when transposing the animal experimentation data to practical use in appraising the hazard, if any, to man.

It should be emphasized again that none of these four is necessarily binding on the Secretary. It was specifically drawn to avoid such rigidity. Rather, the Secretary should have sufficient flexibility within the usual and accepted standards for making a proper determination; at the same time, it seemed desirable to spell out certain "ground rules" as a guide in the exercise of his judgment. It may well be argued that one or more of these criteria step outside the question of strict toxicity of a new additive. Be that as it may, it seems clear in the light of the over-all objectives of the Act that there is necessarily such a close relation between consumption of an additive by humans and its ultimate effect on them that each of these criteria should play some role in the conclusions to be drawn by the Secretary.

Criticisms of So-Called "Licensing Power"

The O'Hara bill has been criticized on the ground that it confers too much authority on the Food and Drug Administration—"licensing power" is the way the critics put it. In answer to this criticism, let me say that the authority to exclude exists today under present law with respect to foods for which definitions and standards of identity have been and will be established. As a result of the findings in the bread-standards proceeding, the proponents of chemical emulsifiers were denied a license—if you will—to offer these materials for use in bread-making.

As to foods other than standard foods, I would pose this question: In the matter of safety, should there be a different and less rigorous standard for nonstandardized foods? I do not believe it could be defended in the consumers' interest.

Elements Essential to Any Bill Dealing with Additives Problem

If the statements of principles enunciated by the various food groups mean what they say, it seems that any bill dealing with this admittedly complex problem must have as a minimum two essential elements. They are: (1) adequate pretesting of such additives and (2) approval by the Food and Drug Administration prior to their intended use as a component of any food. Recognizing these as minimum requirements, we may look for the best possible way for all concerned, including the manufacturer of the additive, the user of the additive, the public and the administrative agency, to translate these principles into legislative action.

It is a fundamental of this bill that the decisional power to exclude poisonous or deleterious chemicals must reside in a federal government agency. I believe the drafters of this bill have, at the same time, recognized the desirability in the first instance, without relying entirely on the courts, of surrounding this grant with such safeguards as will prevent arbitrary action. If it is necessary, without impairing ability to take effective action, to add further brakes on this grant of authority, I hope suggestions along those lines will be made during the course of this panel discussion.

H. R. 9166 may not be the best possible method of carrying out the objectives. We do, however, assert that its provisions embody the minimum requirements which any legislation on this important subject must embrace.

Any bill which falls short of that goal would fail to face up to the problem and responsibility which the tremendous achievements and advances in chemistry in the past decade have thrust upon food manufacturers, manufacturing chemists and the agencies of government charged with concern for the purity of our foods.

I, for one, am certain that out of the discussions on this problem, a successful and satisfactory formula will evolve. **[The End]**

GEORGE L. MAISON, M. D., Discusses

Aspects of the Scientific Functions of the Food and Drug Administration

The President of Riker Laboratories, Inc., Addressed the Public Conference on Food and Drug Law Held in Los Angeles Last May Under the Joint Auspices of the University of Southern California Law School, The Food Law Institute and the Women's Division, Los Angeles Chamber of Commerce

TWO rather disparate facets of the food and drug problem command my attention today. The first is the role played by animal experimentation in the improvement of new pharmaceuticals which has attended our food and drug law. The second is the great need for better support of Food and Drug Administration scientists. Even the most rampant critic will agree that the FDA has brought higher standards of research in the pharmaceutical industry. It has created widespread acceptance of the moral obligation to know a great deal about a new drug before its introduction into commerce. It has stimulated the development of new methods of estimating the safety of a product by animal work before it is tried on man and by carefully controlled clinical trial on man before release for sale. In the process, the FDA has been a telling factor in making our pharmaceutical industry the most productive in the world and in giving it the highest standards.

You are all aware that in relation to new drugs, the FDA is primarily charged with seeing that the drug is safe before it appears in commerce. Secondarily, it is charged with seeing that the new drug is not a swindle perpetrated on the public through fraudulent claims. Thus, in a roundabout way, the FDA comes to survey the efficacy, as well as the safety, of any new drug.

The mechanics of the decision as to safety of a new drug deserve careful study. From data supplied by the manufacturer, the FDA scientists must steer between reefs labeled "Nothing new can be

safe," on the one hand, and "Everything new is a wonder drug," on the other. An outline of the book prepared on each new product may be illuminating. There is no official format for the new-drug application but, however organized, it makes a good-sized book.

The book is started with an introduction presenting in brief the manner in which the drug fits into the scheme of known drugs, the simplified rationale which recommends its use and, especially, the principal drawbacks attending its use. In two or three pages, the story of the drug is outlined.

The section on chemistry follows. Its contents include structure, characteristic reactions which may underlie pharmacologic activity, underlie instability to light or heat, or underlie incompatabilities and, finally, characteristic derivatives which aid in identification. These data are preparatory. They permit the FDA scientist to assure himself that the proposed drug is reproducible and to orient his thinking relative to safety.

The section on pharmacology and toxicology presents the main focus of my own training, and here is where the effects of the FDA are most plainly seen. Before the food and drug law existed, the manufacturer sidestepped animal trials of new drugs to a very great extent, because they were costly, because public opinion was controversial and because animal laboratories are more difficult to police and keep sweet-smelling than other parts of the factory. The acceptance of animal experimentation came about because it is the primary means for assessing safety.

Ideally, the person who has to say a drug is safe for use by or upon his fellow citizens would like to have a complete set of records of the life history of 10,000 persons who had started taking the drug ten years before. He would like some of these people to have died conveniently, so as to present him with a fair number of complete autopsy reports. Obviously, if the administrator turned these desires into demands, he would be accused of (1) keeping unnecessarily from the citizens allegedly life-saving measures, (2) unnecessarily restricting trade and (3) being autocratically indecisive.

It is surprising, and a tribute to the personnel of the Administration, that few such accusations are current. Good animal experimentation provides the first bulwark against such indecision.

The food and drug law has given a great stimulus to the development of methods for estimating safety of potential drugs. Concepts

have developed as a result of that stimulus, and these find themselves represented in the pharmacology and toxicity section of the book.

Data are given of experiments attempting to show how the drug creates its principal action and, in the process, what it does to each of the other organ systems of the animal body. These experiments, as well as those to be described later, are done on more than one species of animal because the rat or rabbit, though they are herbivores, the cat, though a carnivore, and the dog, though in some sense an omnivore, all closely parallel man in certain body functions. Such experiments alert the clinician as to where to look for important side actions.

Here, too, are experiments in which more than one drug is given at a time and combined effects recorded. A drug is not safe just because it can be used alone without damage. Interaction with foods and other drugs apt to be used concomitantly must be looked for.

Experimentation with Animals

Experiments in which the recipients are animals in special conditions are frequently included. A drug is not safe just because it can be accepted without toxicity by an individual in middle life. Special reactions must be sought in the very young and the very old, the male and the female, and the expectant mother and the child she carries. Animals offer a ready means of primary test of such interactions.

Administration of the drug in higher and higher dosage until lethality is produced provides information on the factor of safety over the dose required to achieve the clinically desired action. The manner of death produces valuable leads as to sensitivity reactions which may be induced in man.

A drug is not safe just because most individuals can take it without damage. It must be safe for the most sensitive individual or its action must be so important to continuing life that a risk of drug damage is justified. In this event, the nature of the damage it may cause must be clearly elucidated so that the physician may be forewarned as to the premonitory signs of the typical drug toxicity.

The results of prolonged administration of the drug in very high dosage to animals of a short life span provide an approach to learning the potential long-term effects of the drug on man. Here, again, the use of several species is required. The actual duration of the chronic

administration is tailored to the probable duration of human medication with the agent: longest for a food additive or a drug which will be taken for the rest of a patient's life, shortest—but rarely less than a month—for a drug which will be taken once in an emergency. Animals used for such chronic-toxicity studies are humanely killed at the end of the appropriate period, and careful examination of their organs follows. Prolonged experience in evaluating animal data of this kind has produced rules of thumb which are of great significance to the estimation of probable safety.

Passing rapidly over the remaining sections of the book: "Formula" covers a concise statement of components which will be found in the product in its marketable condition, and their quantities. "Methods of Manufacture" provides a description of how those items came to be there. The "Assay" section details how the exactness and uniformity of content can be measured. "Control Methods" details specifications for each component and methods of test to insure its purity.

"Labelling," as a section title highlights the legal interpretation of the word "label" as applied to food and drug cases., The section includes both the facsimiles of the proposed labels and the brochure for the physician. The brochure details the claims about the drug which, because of our knowledge, we feel justified in making. In the case of drugs for prescription use only, which by some quirk of human thought are called "ethical drugs," this brochure is the most important focus of the whole book.

Because the data of the "Clinical Reports" section justify the claims made in the labeling, this section comes last. The key items in the data presented include: an adequate number of reporting physicians, an adequate number of patients who have used the drug, an adequate duration of time during which each individual took the drug—with inclusion of patients who had at least the common unrelated conditions of age, pregnancy and disease. It is axiomatic that the reports from physicians who were unfavorably impressed with the drug must be included with the favorable reports.

With the best of data, the job of releasing a drug as safe is an unenviable one. I think we have been most fortunate in the scientists with the FDA in recent years. Their devotion has largely been unappreciated by the public, and certainly inadequately rewarded. In

order to evaluate their contribution, let us note that a scientist likes to go his own way, peering into the unknown from a vantage point of his own choosing. In large measure, these men give us this privilege. Instead, they spend their time critically examining the work of others and repeating parts of experiments presented to them, to insure their verity. The milieu in which they work is alive with dissatisfied customers whose eyes have been blinded by their desire to have the object of their developments prove good for man and lucrative for their business. Their milieu is political Washington.

One grave question which bothers me is: How long will we continue to have good scientists in the FDA? By an act of Congress last year, these men were specifically prevented from attending scientific meetings at government expense. Attending meetings and keeping up to date is a favorite perquisite of scientists. The total funds available for operation of the Administration appears to me pitifully small. If my impressions are correct, this situation should be a cause for deep concern on the part of the citizenry. It remains for informed individuals to make their opinions known if continuing starvation of the FDA is to be avoided.

The budget for the FDA has only been doubled since 1941—$2,518,683 then, $5,228,220 for fiscal 1954. Actually, last year Congress cut the departmental budget by 7 per cent from the $5,600,000 provided in fiscal 1953. Meanwhile, costs have more than doubled and duties have continued to expand with a growing population, an enlarging list of drugs to be studied and a steadily increasing gross national product. The FDA cannot afford to hire as many personnel today as it could afford in 1941 (826 today, 831 then). Certain functions have had to be abolished to retain the present personnel level.

I hope that these remarks will incite you to get intelligent people to write to their Congressmen stating their concern over an adequate FDA. Let me also say that I am generally opposed to expansion of the activities and budgets of the federal government. The FDA function is one which I do not believe can practically or economically be relegated to the states. If I am wrong and it is feasible to reduce FDA work by this means, then I should like to see the states take over. But monetary emasculation of the FDA, with languishing of services critical to health, is not the way to enforce the shift from national to state function. **[The End]**

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